MEDI-CAL DRUG USE REVIEW (DUR) BOARD

State of California
DEPARTMENT OF HEALTH CARE SERVICES

Notice is hereby given that the **Medi-Cal DUR Board** will conduct a public meeting on **Tuesday, November 15, 2016,** at the following location:

Department of Health Care Services
1500 Capitol Avenue
Training Rooms B+C
Sacramento, CA 95814

Medi-Cal Drug Use Review Board
Meeting Agenda
November 15, 2016
9:30 AM-12:30 PM

Report Type*	Agenda Item	Presenter	Time
C	**1.** Welcome/Introduction	Pauline Chan, RPh, MBA	930-945
A	**2.** Call to Order/Review and Approval of Previous Minutes from September 20, 2016	Robert Mowers, PharmD	945-950
	3. Old Business		
A	**a.** Review of Action Items from Previous Board Meeting: i. Opioid Quantity Limit Policy ii. State Opioid Workgroup iii. FFY 2015 DUR Annual Report to CMS iv. Educational Outreach: Asthma v. Educational Outreach: Buprenorphine vi. Educational Outreach: Metabolic Monitoring vii. Retrospective DUR Review: Proton-pump Inhibitors	Pauline Chan, RPh, MBA	950-1005
	4. New Business		
R/A/D	**a.** Board Activities	DUR Board	1005-1010
	i. Buprenorphine Study Proposal	Randall Stafford, MD, PhD	1010-1020

R/A	**b.** Quarterly Report: 3Q2016 (July – September 2016) **c.** Review of Physician Administered Drugs (PADs): 2Q2016 (April – June 2016) **d.** Prospective DUR i. Review of DUR Alerts for New GCNs: 3Q2016 ii. Section 25 Update – Therapeutic Categories **e.** Review of DUR Educational Outreach to Providers i. Update: Metabolic Monitoring Letter - 2016 ii. Update: Buprenorphine Letter	Amanda Fingado, MPH	1020-1050
R/A/D	**f.** Retrospective DUR i. Review of Retrospective DUR Criteria: Hepatitis C Virus (HCV) Drugs ii. Review of Retrospective DUR Criteria: New Additions to the Medi-Cal List of Contract Drugs (FFY 2015) iii. Review of Retrospective DUR Criteria: Concomitant use of Opioids and Benzodiazepines **g.** Review of DUR Publications i. DUR Educational Alert (September, 2016): Vaccine Update ii. Discussion/Recommendations for Future Bulletins	Shalini Lynch, PharmD	1050-1130
R/D	**h.** Global Data Sharing (state & counties) and Public Reporting of Psychotropic Medication Use in Foster Care Children & Youth	Akhtar Khan, PhD, Chief, Research Services, CDSS	1130-1150
R/A/D	**i.** Overview of the Institute for Clinical and Economic Review (ICER)	Stephen Pearson, MD, MSc, President, ICER	1150-1205
R/A/D	**j.** Pharmacy Update i. CMS Update ii. Academic Detailing Conference iii. Medi-Cal Managed Care Pharmacy Directors Meeting iv. DHCS Quality Strategy v. SB 238 Foster Care Psychotropic Medications vi. CDPH Collaboration: Improve Pre-natal Vitamin Use	Pauline Chan, RPh, MBA	1205-1225
C	**5.** Public Comments		1225-1230
	6. Consent Agenda		
I	**a.** Meeting feedback **b.** Next meeting: February 21, 2017 9:30 AM -12:30 PM Xerox State Healthcare, LLC 840 Stillwater Road, Mendocino Room West Sacramento, CA 95605 **c.** DUR Board Meeting Dates for 2017: Tuesday, May 16, 2017 Tuesday, September 19, 2017 Tuesday, November 21, 2017		
	7. Adjournment		1230

* REPORT TYPE LEGEND: **A: Action**; **R: Report**; **I: Information**; **C: Comment**; **D: Discussion**

** Comments from the public are always appreciated. However, comments will be limited to five minutes per individual.

Picture identification is required to gain access into the California Department of Health Services building. However, your security information will not be provided to the DUR Board.

You can obtain the DUR Board agenda from the Medi-Cal DUR Main Menu Web site (http://files.medi-cal.ca.gov/pubsdoco/dur/dur_home.asp).

MEDI-CAL DRUG USE REVIEW BOARD
MEETING MINUTES
Tuesday, September 20, 2016
9:30 a.m. – 12:30 p.m.

Location: **Xerox State Healthcare, LLC**
840 Stillwater Road
Monterey Room
West Sacramento, CA 95605

Topic	Discussion
1) CALL TO ORDER/ WELCOME/ INTRODUCTION	• The meeting was called to order by the Chair of the Board, Dr. Robert Mowers. • Board members present: Drs. Andrew Wong, Randall Stafford, Robert Mowers, Patrick Finley, Timothy Albertson, Janeen McBride, and Marilyn Stebbins. • Board members absent: none. • Board members and attendees introduced themselves. • Pauline Chan, RPh was present from DHCS Pharmacy Benefits Division. • Ivana Thompson, PharmD (Xerox) announced that the DUR Board meeting is being recorded and reminded everyone to sign the attendance sheet. She also let everyone know that if they weren't already signed up for the Medi-Cal Subscription Service (MCSS), a representative from MCSS would be available during the meeting to facilitate enrollment. • Ms. Chan announced that Dr. Thompson was leaving the group and thanked her for her years of service.
2) REVIEW AND APPROVAL OF MAY 2016 MINUTES	The Medi-Cal Drug Use Review Board (the "Board") reviewed the May 17, 2016 minutes. Dr. Wong noted he had minor edits and motioned that the minutes be approved with these changes. There was no discussion. The Board voted unanimously to approve the minutes as edited by Dr. Wong. **ACTION ITEM**: Incorporate Dr. Wong's edits into the minutes and post to the DUR website.
3) OLD BUSINESS	**a.** Review of Action Items from Previous Board Meeting: i. Pregnancy Alert: Updated – Dr. Thompson reported that per the Board recommendations at the May 17, 2016 DUR Board meeting, the pregnancy alerts that were in test mode are now turned on. Dr. Thompson also reported that the DUR manual has been updated to reflect the changes in the pregnancy alert. ii. Drug-Drug Interaction Alert: DUR Manual Updated – Dr. Thompson stated that the outdated drug-drug interaction table in the DUR manual has been removed and the manual has been updated to reflect the correct information about the drug-drug interaction alert. iii. Anticholinergic Provider Letter: Sent – Dr. Thompson reported the anticholinergic letter was sent to providers and Amanda Fingado, MPH (UCSF) will report on this in more detail later in the meeting. iv. PCSK9 Inhibitor: Update RetroDUR in May 2017 – Dr. Thompson reminded the Board that due to the current low utilization of PCSK9 inhibitors in the Medi-Cal fee-for-service population, the Board had motioned to revisit this topic again in one year. v.

4) NEW BUSINESS	**a.** Board Activities: Ms. Chan reminded the Board that the academic detailing best practices conference is scheduled for October 20, 2016 at DHCS. Ms. Chan thanked Drs. Andrew Wong and Randall Stafford for their assistance with conference preparations.

b. Presentation: "Adult Immunizations and Pharmacies" – Eileen Yamada, MD, MPH from the California Department of Public Health Immunization Branch presented along with Lisa M. Ghotbi, PharmD from the San Francisco Health Plan who shared some plan-specific data related to adult immunizations.

Dr. Yamada began her presentation by stating that vaccine-preventable diseases in adults are common, but immunization rates are low. Vaccine-preventable diseases include influenza, invasive pneumococcal disease (IPD), pertussis, hepatitis B, and herpes zoster (shingles). A review of California vaccination data from 2014 showed the pneumococcal vaccine rate among adults > 65 years of age was 70% (compared with a Healthy People 2020 target of 90%), influenza vaccine among adults 18 years of age and older was 43% overall (Healthy People 2020 target of 90%), and even lower among Latinos (37%) and African-Americans (36%). Dr. Yamada reported the shingles vaccination rates among adults 60 years of age and older was 36%, which exceeds the Healthy People 2020 target of 30%.

Dr. Yamada reported on California's most recent pertussis epidemic in 2014, where there were approximately 345 verified pertussis cases. Reported Medi-Cal hospitalization charges for infants < 150 days of age were approximately $33 million. Individual hospitalization charges where Medi-Cal managed care plans were the payer ranged from approximately $13,000 to $413,000. Dr. Yamada stated that to prevent pertussis disease and complications in young infants, Tdap is recommended at 27-36 weeks gestation for each pregnancy, regardless of prior Tdap. She presented regional data on the receipt of Tdap vaccine by pregnant women in California during 2014, showing geographic variation ranging from a 33% vaccination rate in the southeastern area to a 71% vaccination rate in the San Francisco Bay area.

Dr. Yamada also spoke about recommendations for all women who are, or will be, pregnant during flu season to receive influenza vaccination, regardless of trimester of pregnancy. Dr. Yamada pointed out that Medi-Cal influenza immunization rates during pregnancy are much lower (33%) than among pregnant women with private health insurance (56%). Again Dr. Yamada presented regional data on the receipt of influenza vaccine by pregnant women in California during 2014, showing similar geographic variation (29% vaccination rate in the southeastern area to a 67% vaccination rate in the San Francisco Bay area).

Dr. Yamada then referred to Medi-Cal managed care plan (MCP) contractual requirements that state that the contractor is responsible for assuring all adults are fully immunized. She reported that pharmacists could help contractors meet these obligations. Dr. Yamada reported initial concerns were raised about pharmacy-delivered adult immunization, considering immunizations were already established as a medical benefit. However, Dr. Yamada pointed out that many adult providers do not stock some or all recommended adult vaccines because they are too expensive (cost of vaccines, storage, etc.), staff many not be trained to administer all needed vaccines, while some providers reported already referring to pharmacies for immunization. By allowing pharmacies to administer immunizations as part of the pharmacy benefit, pharmacists can provide an important immunization resource for the community when recommended vaccines are not otherwise available. She also clarified that adults 19 years and older are not covered by the Vaccines for Children Program (VFC). Dr. Yamada also clarified that many large chain pharmacies have immunization services built into their workflow and are already reporting into the California Immunization Registry (CAIR). She also stated that under-immunization is of much greater concern than over-immunization, with any potential extra costs overshadowed by the cost-savings of a hospitalization due to a vaccine-preventable disease.

Dr. Yamada also spoke about recent pharmacist-related legislation, including Business & Professions (B&P) Codes Sections 4052 (a) (11) and 4052.8, which gives trained pharmacists the authority to administer recommended immunizations for persons 3 years of age and older. Dr. Yamada also described new regulations (Title 16 CCR Section 1746.4) that require pharmacists administering immunizations to keep documentation of the

completion of their specialized training, compete continuing education once every two years, notify each patient's primary care provider of each vaccination, report each vaccination into CAIR, and keep all immunization records easily accessible. She also informed the Board that as of February 1, 2016, the following vaccines on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices were added to FFS CDL without a Treatment Authorization Request (TAR):

Tdap, Hepatitis A, Hepatitis B, HepA-HepB, HPV, influenza, MMR, MenB, MenACWY (MCV4), MPSV4, PCV13, PPSV23, rabies, Td, varicella, zoster

Dr. Yamada also reported that on August 31, 2016, a letter was sent to all Medi-Cal managed care health plans to clarify that managed care plans must also provide adult immunizations (similar to Medi-Cal FFS) on their pharmacy formulary.

Dr. Yamada concluded by providing resources for more information, including http://eziz.org, a website maintained by the Vaccines for Children Program and the California Immunization Registry website, where there is information about CAIR2, which is currently in the transition phase from CAIR.

Dr. Ghotbi then spoke about San Francisco Health Plan (SFHP) and their pharmacy vaccine benefit, which was effective October 1, 2015. She first provided some background on SFHP, which provides health insurance for one out of every six San Francisco residents and 80% of Medi-Cal eligible San Francisco residents. Dr. Ghotbi stated there are approximately 140,000 members currently enrolled in SFHP and that SFHP spent approximately $72 million on pharmacy claims in 2015.

Dr. Ghotbi then described the SFHP pharmacy vaccine benefit, which is restricted to Medi-Cal members 19 years of age and older. Pharmacists are reimbursed the ingredient cost, a $1.50 dispensing fee, and a $9.50 administration fee. Since October 1, 2015 the pharmacy benefit has included the following vaccines (with HPV and rabies added February 2016):

- Influenza, MMR, meningococcal, pneumococcal, herpes zoster, Td/Tdap, Hib, and varicella.

Dr. Ghotbi presented some initial findings of the implementation of this vaccine pharmacy benefit to SFHP, based on data through April 2016. They found that paying twice for a vaccine is not materializing as a problem, pharmacy registration of immunizations is about 80-90% (higher than physicians), and that all providers are viewing this as a positive change. While the majority of vaccines at the pharmacy were for influenza (83%), there were some additional vaccines administered, including herpes zoster, Tdap, pneumococcal, MMR, varicella, Hib, and meningococcal.

Dr. Stebbins asked Dr. Yamada and Dr. Ghotbi if they knew if pharmacies could now be VFC providers. Dr. Yamada said she thought they could be if they met all of the requirements but that she was not sure. Dr. Mowers inquired if there are any public service announcements to promote these changes to immunization policy in California and would encourage patients to go to their pharmacy for vaccinations. Dr. Yamada said that there are many campaigns led by CDPH to improve immunization rates and that she would look into whether this particular aspect was going to be included on future patient education materials. Dr. Stebbins wondered if anyone had reviewed why the San Francisco Bay Area vaccination rates were so high. Dr. Yamada stated that this area has excellent outreach and task forces focused on vaccinations.

c. Presentation: "Medi-Cal Payment Error Study (MPES)"– Mark Mimnaugh, RN, CCRN, MPA, the Chief of the Medical Review Branch, Audits and Investigations Division, presented results from the 2013 MPES, which estimated dollar loss in the Medi-Cal Fee-For-Service (FFS) programs by identifying payment errors, stratified by non-fraud and potential fraud. Mr. Mimnaugh stated that MPES improved anti-fraud prevention by zeroing-in on current risks.

Mr. Mimnaugh described the MPES methodology, which used FFS and dental claims paid during the 4th quarter of 2013 grouped into strata, with each stratum representing a major provider type. He noted that 2013 data are used for this report, as it takes two years to complete the study. A random sample is then drawn for each stratum with a minimal sample size of 50 per stratum and a ratio estimator is used to develop the overall payment error rate which is weighted by amounts paid within each stratum. He stated that a subset of the payment error rate was also estimated to measure the potential fraud.

Mr. Mimnaugh then summarized the data, showing the breakdown of both total paid claims and reimbursement dollars paid by provider. He then described the field work conducted in which the Medical Review Branch conducted site visits to each provider in the sample and found that 92% of payments were paid correctly, 6% of payments contained errors (not fraud), and almost 2% of payments may be the result of potential fraud. Mr. Mimnaugh then showed data summarizing payment error and potentially fraudulent errors by provider type, comparing the findings from MPES 2013 to previous MPES work dating from 2005. Across all MPES reports pharmacy providers are either ranked 1st or 2nd for payment errors.

Mr. Mimnaugh then provided several examples of claims errors from across multiple provider types. He stated that the MPES 2013 study found potential fraud characteristics may include the following:

- No documentation provided of the service for the claimed date.
- No documentation submitted that indicates that the services were provided by trained health care aides, supervised by a licensed health professional.
- Overbilling by a pharmacy for equipment.
- No documentation provided by a pharmacy for a medication refill.
- No documentation of the service was received to support the claim.

He concluded by discussing emerging risks in the Medi-Cal managed care population, stating that DHCS may attempt to develop a new MPES methodology for managed care claims. Finally, Mr. Mimnaugh informed the meeting that Medi-Cal Payment Error Study Reports are available at the Audits and Investigations Branch website.

Dr. Mowers questioned an example given by Mr. Mimnaugh that found payment error at the pharmacy after a *Treatment Authorization Request* (TAR) had been approved by a prescriber. The Board agreed that the pharmacy did not seem culpable for this error given the prescription had an approved TAR. Mr. Mimnaugh stated that the TAR office has one level of review but that there is a higher level of review conducted as a part of MPES and at that time the prescriber had failed to provide any documentation to support the claim, so it was recorded as a payment error at the pharmacy.

d. DUR Annual Report to the Centers for Medicare & Medicaid Services (CMS) – Ms. Chan and Dr. Thompson reviewed the DUR annual report for Federal fiscal year (FFY) 2015, which is due to CMS by September 30, 2016. Ms. Chan highlighted several of the changes and additions to the annual report survey, including the following:

- Page 3, question 5: Ms. Chan stated that while in FFY 2015 there was no follow-up with providers who routinely overrode DUR alerts, this is something that may be changing in the future.
- Page 7: Ms. Chan stated that while prospective DUR is not conducted on physician-administered drugs (PADs), the program has been conducting quarterly retrospective DUR reports on utilization and presenting these to the Board.
- Page 8: Ms. Chan pointed out the generic utilization data for FFY 2015. Dr. Mowers asked if CMS allowed us to define certain brand names as generic, given the cost difference after supplemental rebates makes some branded drugs just as or more cost-effective than some generic options. Ms. Fingado stated that the file containing these codes comes directly from CMS and is listed by National Drug Code (NDC). Dr. Thompson agreed that CMS does not allow us to define any brand-name drug as a generic. Ms. Fingado pointed out that the generic drug percentage for California is significantly impacted by the presence of carved-out drugs, which are typically branded and more expensive drugs. Dr. Thompson also

confirmed that no supplemental rebate information is included in the annual report. All cost data listed are reimbursement dollars paid to pharmacies.

- Page 15: Ms. Chan went through some of the new survey questions looking at the utilization of opioids. She pointed out that the new questions ask about point-of-sale edits in place to limit the quantity of opioids in both days' supply and units per day. She described the current edits for California are not linked to either of these metrics so it was difficult to interpret these questions, especially when not given another option to choose. Ms. Chan stated that California has edits in place for opioids, including a maximum amount per dispensing that varies by drug and a limit of three dispensings within any 75-day period.
- Page 16: Ms. Chan reported that the state opioid group is working to define a daily maximum of morphine equivalency. Dr. McBride commented that perhaps state Medicaid should follow the Medicare recommendations of a morphine equivalent daily dose (MEDD) of 120 mg. Dr. Finley asked if there was any movement within policy to change how we limit opioids, for example to change to a 30-day supply? Dr. Finley stated that three dispensings within a 75-day window seemed not to align with what all other states are doing. Dr. Mowers asked if the Board could make a motion to align with Medicare guidelines. Dr. Finley motioned to evaluate replacing the current policy of a maximum of three dispensings of opioids within any 75-day period to a maximum supply of 30 days. The motion was seconded and carried.

ACTION ITEM: The DUR Board recommendation to evaluate replacing the current policy of a maximum of three dispensings of opioids within any 75-day period to a maximum supply of 30 days will be submitted to DHCS.

- Dr. Mowers then motioned for a comprehensive evaluation of opioid policy across states, aligning where feasible with national policy. Ms. Chan commented that this could be problematic because, for example, while Medicare published a MEDD of 120 mg as a maximum, the CDC has published 90 mg. Dr. Stafford stated that even within California state agencies there are discrepancies as to the cutoff for MEDD. Ms. Chan suggested that it may be beneficial to the DUR program to have a Board member participate in the state opioid workgroup, where this work has been ongoing. Dr. Mowers amended his earlier motion to support this suggestion, and motioned to recommend a member of the Board participate in the state opioid workgroup.

ACTION ITEM: The DUR Board recommendation to have a DUR Board member participate in the state opioid workgroup will be submitted to DHCS.

- Finally, a motion was made – and seconded – to approve the DUR Annual Report for FFY 2015 to CMS for submission. There was no further discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendation to approve and submit the FFY 2015 DUR Annual Report to CMS will be submitted to DHCS.

e. Quarterly Report – 2Q2016 (April – June 2016): Ms. Fingado reported that in 2016 Q2, the total reimbursement paid to pharmacies decreased by double digits in comparison to the prior quarter, most likely due to labeler restrictions being changed or removed for several high-volume and/or high-cost drugs effective April 1, 2016, including QUETIAPINE, OLANZAPINE, and ATORVASTATIN CALCIUM. Ms. Fingado cautioned that while the reimbursement paid to pharmacies decreased by 16% from the previous quarter, the actual net change in expenditures is unknown due to California's supplemental rebate program.

f. Review of Physician Administered Drugs (PADs) – 1Q2016 (January – March): Ms. Fingado showed a summary of paid claims for physician-administered drugs for the 1st quarter of 2016, which includes paid claims with dates of services between January 1, 2016, and March 31, 2016. These data were presented in three tables: 1) the top 20 drugs by total reimbursement paid, 2) the top 20 drugs by utilizing beneficiaries, and 3) the top 20 drugs

by reimbursement paid to pharmacies per utilizing beneficiary. Ms. Fingado reported decreases in both total utilizing beneficiaries (a 36% decrease) and total paid claims (a 21% decrease) from 4Q2015 to 1Q2016 in the category "PHYSICIAN ADMINISTERED DRUG – NDC NOT REQUIRED," which can be attributed to the influenza vaccine having peak utilization in Q4 each year. Among all three categories of physician-administered drugs, Ms. Fingado pointed out decreases in both total utilizing beneficiaries and total paid claims from 1Q2015 to 1Q2016. Ms. Fingado stated that these decreases are most likely due to the migration of dually-eligible beneficiaries into the Cal MediConnect program during 2015 and continued migration of other Medi-Cal beneficiaries from the fee-for-service program into managed care health plans.

g. Prospective DUR reports were presented by Amanda Fingado

i. Review of DUR Alerts for New GCNs in 2Q2016 (April – June 2016)

- At each DUR Board meeting, a list of new GCN additions with prospective DUR alerts turned on other than ER and DD will be provided to the DUR Board for review. For this meeting, the DUR Board reviewed the alert profiles of the following eighteen GCNs:
  - GCN # 075729: GABAPENTIN/LIDOCAINE/MENTHOL – Drug Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCNs #068868 and #068870: MORPHINE SULFATE/0.9% NACL/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #075812: EMTRICITABINE/TENOFOV ALAFENAM – Ingredient Duplication (ID)
  - GCN #071205: ACETAMINOPHEN – Ingredient Duplication (ID), High Dose (HD)
  - GCNs #075849 and #075850: METHOTREXATE/PF – Drug-Pregnancy (PG)
  - GCN #075823: NAPROXEN/CAPSI/MENTHOL/ME-SAL – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #075811: DICLOFEN SOD/KINESIOLOGY TAPE – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #070009: FENTANYL CITRATE-0.9 % NACL/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #075855: GABAPENTIN/CAPSI/ME-SAL/MENTH – Drug Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #075937: CELECOXIB/CAPSAICIN/MENTHOL – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #075893: DIPHENHYDRAM/PE/DM/ACETAMIN/GG – Ingredient Duplication (ID), High Dose (HD)
  - GCN #076001: MORPHINE SULFATE – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCNs #076031, #076032, #076033, #076034, and #076035: OXYCODONE HCL – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #076023: ACETAMINOPHEN/ D-BROMPHENIRAMIN – Ingredient Duplication (ID), High Dose (HD)
  - GCN #075937: CELECOXIB/LIDOCAINE/MENTHOL – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
  - GCN #076025: PIMAVANSERIN TARTRATE – Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD)

- GCNs #076097, #076101, and #076102: EMTRICITABINE/TENOFOVIR – Ingredient Duplication (ID)
- GCN #076131: DICLOFENAC/ME-SALIC/MENTH/CAMP – Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #076079: DOXYCYCLINE MONOHYDRATE – Drug-Pregnancy (PG)
- GCNs #076198 and #076200: MORPHINE SULFATE/0.9% NACL/PF – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCN #076221: FENTANYL CITRATE – Drug Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
- GCNs #076226 and #076227: DOLUTEGRAVIR SODIUM – Ingredient Duplication (ID)
- GCNs #076256 and #076257: LINAGLIPTIN/METFORMIN HCL –Drug-Disease (MC), Therapeutic Duplication (TD), High Dose (HD), Low Dose (LD)
- GCN #076152: DICLOFENAC SODIUM– Drug Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)

- A motion was made – and seconded – to accept these alert profile recommendations. There was no discussion. The motion was carried.

h. Review of DUR Educational Outreach to Providers

i. Update: Anticholinergic Letter

- Ms. Fingado presented updated outcomes from the provider letter aimed at improving the quality of care among Medi-Cal fee-for-service beneficiaries age 65 years and older with concomitant use of second-generation antipsychotic and anticholinergic medications. She described a change in the methods from the original proposal, which had stated inclusion criteria of six or more paid claims of second-generation antipsychotic medications and six or more paid claims of anticholinergic medications. Ms. Fingado reported that the claims data show a large majority of paid claims were for less than a 30 days' supply. Modified inclusion criteria instead defined regular use as the use of both a second-generation antipsychotic medication and an anticholinergic medication, each with a total days' supply greater than 180 days during the measurement year (between May 1, 2015, and April 30, 2016).
- Ms. Fingado reported that a total of 152 beneficiaries met inclusion/exclusion criteria for the mailing. A total of 130 prescribers were identified for educational outreach letters and a total of prescriber letters were mailed on June 17, 2016.
- Ms. Fingado reported that for this letter approval was received from DHCS to use National Provider Identifier (NPI) mailing addresses for all providers not listed in the Medi-Cal Provider Master File. A little less than half of the providers for this mailing were not listed in the Medi-Cal Provider Master File (n=53; 41%).
- Ms. Fingado summarized the outcome data thus far for this mailing, including the following:
  - Rate of undeliverable letters (within 90 days):
    - Thus far, after 60 days, 16 prescribers (out of 130 unique prescribers) had their letters returned to sender as undeliverable, for an undeliverable rate of 12%.
    - The rate of returned mail among those providers with addresses in the Medi-Cal Provider Master File is higher (14%) when compared to providers with addresses obtained from their NPI (9%).
  - Provider response rate (within 90 days):
    - Thus far, after 60 days, a total of 15 prescribers (out of 130 unique prescribers) returned 15 patient surveys, for a provider response rate of 12%. The response rate is similar among those providers with addresses obtained from the NPI file (11%) and those listed in the

Medi-Cal Provider Master File (12%)
        - If undeliverable letters are removed from the denominator, the response rate increases to 13% (15 out of 114 unique prescribers)
        - The 15 patient surveys received thus far represent 10% of patient profiles in this mailing
    - As stated in the original proposal, the following outcome variable will be assessed at a later time point, as medical and pharmacy claims data become available:
        - The primary outcome variable will be the percentage of the continuously-eligible study population with a total days' supply greater than 90 days for both an anticholinergic and an atypical antipsychotic in the 6-month period following the mailing of the intervention letter (July 1, 2016 through December 31, 2016).
- Dr. Stafford clarified that the process was to check the Medi-Cal Provider Master File first, and then to refer to the NPI registry for those without entries in the Provider Master File. Ms. Fingado stated that this was the current process and reported that all address data must be submitted for review by DHCS prior to mailing. Dr. Thompson stated that the process may be more efficient in the near future, as data from the NPI file will be available at the same time as the data from the Provider Master File, allowing immediate comparison between the two. She estimated these data will be integrated into the current database before the end of 2016.
- Adam Kaye, PharmD suggested that physicians prescribing other drugs besides antipsychotics could benefit from a similar letter, especially those prescribing anticholinergics to patients with Alzheimer's disease and dementia, for example. Ms. Fingado agreed that this particular letter could be a template for future outreach to providers who prescribe anticholinergics to other high-risk populations.

ii. Update Outcomes: Asthma Letter

- Ms. Fingado reported on updated outcomes from the asthma provider letter sent in May 2015. The following primary outcome variable was assessed at 90-days following the packet mailing date in the subgroup of continuously eligible Medi-Cal FFS beneficiaries:
    - Percentage of beneficiaries with an outpatient visit in which asthma was one of the listed diagnoses (by control and intervention groups, in aggregate).
- Medical and pharmacy claims data with dates of service between May 1, 2015 and August 31, 2015 were reviewed. Ms. Fingado reported that there was one beneficiary from the control group that was no longer enrolled in the Medi-Cal fee-for-service program as of July 2015, which left 16 beneficiaries in the control group and 16 beneficiaries in the intervention group.
    - Outpatient visits within 90 days of mailing: control group (2/16 = 12%)
    - Outpatient visits within 90 days of mailing: intervention group (1/16 = 6%)
    - One of the two control beneficiaries with an outpatient office visit also had two visits to the emergency department during this timeframe.
    - No other beneficiaries had paid claims for emergency department visits or inpatient hospitalizations within 90 days of the mailing.
- Ms. Fingado also reported on the following secondary outcome variable, which was assessed at six months following the packet mailing date in the subgroup of continuously eligible Medi-Cal FFS beneficiaries:
    - Total reimbursement paid to pharmacies for all asthma-related pharmacy claims by individual utilizing beneficiary
        - Control (n=14): average increase of $130.70 per beneficiary
        - Intervention (n=14): average increase of $241.24 per beneficiary
    - Total reimbursement paid to pharmacies for all asthma-related pharmacy claims by group (in aggregate):
        - Control (n=14): $1968.77 during the 6 months prior to the mailing vs. $3798.63 during the 6 months following the mailing
        - Intervention (n=14): $2776.94 during the 6 months prior to the

mailing vs. $6154.26 during the 6 months following the mailing

- Ms. Fingado also reported on the following secondary outcome variables for the 12 months following the packet mailing date in a subgroup of 28 continuously eligible Medi-Cal FFS beneficiaries (n=14 in the control group and n=14 in the intervention group):
    - Percentage of beneficiaries with an AMR ≥ 0.50 (among beneficiaries still taking any medication for asthma):
        - Control: 1/8 = 13%
        - Intervention: 4/7 = 57%
    - The net change in AMR by individual utilizing beneficiary (among beneficiaries still taking any medication for asthma):
        - Control (n=8): +0.01
        - Intervention (n=7): +0.25
    - Rate of emergency department visits where the primary diagnosis is asthma (by control and intervention groups, in aggregate):
        - Control (n=14): 1/14 = 7%
        - Intervention (n=14): 3/14 = 21%
    - During this time period there were no inpatient hospitalizations in either group where the primary diagnosis was asthma.
- Ms. Fingado pointed out that due to the small sample size, further evaluation would be underpowered. Dr. Albertson asked if it would be possible to expand the study to a larger number of patients. Ms. Fingado stated that the original mailing was intended to be a pilot study on the feasibility and acceptability of including patient data in educational outreach letters to providers and that the original inclusion/exclusion criteria were very limiting. She suggested that it could be replicated and expanded using less strict criteria, particularly a shorter interval without an office visit.

- A motion was made – and seconded – to accept Dr. Alberton's proposal to repeat this educational outreach using less restrictive inclusion/exclusion criteria. There was no further discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendation to conduct expanded educational outreach to providers regarding asthma quality-of-care will be submitted to DHCS.

iii. Updated Outcomes: MEDD Letter

- Ms. Fingado reported that on July 21, 2016, a total of 23 returned mailings were re-sent with updated patient profiles (claims data through June 30, 2016) to new prescriber addresses found using NPI address data. As of August 16, 2016, of the 23 letters that were resent only one of these has been returned as undeliverable and a total of five of these prescribers have returned patient surveys. Including these surveys, the response rate is now 23% for this mailing (up from 17%).
- Ms. Fingado also provided the following summary of the 34 survey responses obtained thus far:
    - A total of 27 patient surveys (79%) indicated that the patient was currently under their care
    - A total of 5 patient surveys indicated that the provider would prescribe naloxone for the patient
    - A total of 11 patient surveys contained written comments from providers, with the majority of comments (55%) discussing a tapering/weaning plan either in process or completed
- As stated in the original proposal, Ms. Fingado will assess the following outcome variables at later time points, as medical claims data become available:
    - The primary outcome variable will be the percentage of the continuously-eligible study population with a paid claim for an opioid medication exceeding > 120 mg MEDD in the 6-month period following the mailing of the intervention letter (April 1, 2016 through September 30, 2016)
    - The following secondary outcome variables will be assessed in the 6-month period following the mailing of the intervention letter (April 1, 2016 through

September 30, 2016):
    - Percentage of the continuously-eligible study population identified as receiving prescription opioid medication as part of a narcotic withdrawal treatment plan
    - Percentage of the continuously-eligible study population identified with hospital or emergency department visits due to opioid overdose
    - Percentage of the continuously-eligible study population identified as having a paid claim for naloxone in the 6-month period
  - The number of days with cumulative MEDD > 120 mg in the 6-month period prior to the mailing of the intervention letter compared to the number of days with cumulative MEDD > 120 mg 6-month period following the mailing of the intervention letter, by beneficiary (in the continuously-eligible study population)
- Dr. Albertson commented that these data are encouraging. Ms. Fingado stated that final, updated outcomes for this educational outreach would be reported at the May 2017 DUR Board meeting.

iv. Proposal: Buprenorphine Letter

- Ms. Fingado reported that buprenorphine, both by itself and in combination with naloxone, has emerged as a first-line treatment for opioid addiction. Several reviews have concluded there is high-quality evidence to show that medication-assisted treatment (MAT) of opioid addiction with buprenorphine is effective in the maintenance treatment of opioid addiction and increases retention in treatment. Despite the data, this treatment remains highly underutilized and access is often restricted. In 2013, CMS reported that prior authorization for buprenorphine use was required by 48 Medicaid programs and several states had lifetime limits on buprenorphine, even though evidence shows that opioid addiction is a chronic condition that may require ongoing treatment.
- Ms. Fingado described recent efforts at the state and national level to expand access and remove restrictions to buprenorphine, including modification of legislative rules to increase the number of patients that providers are able to treat. As of August 8, 2016, qualified prescribers may now treat up to 275 patients (up from 30 patients in 2000) to allow greater access to buprenorphine-based MAT.
- Ms. Fingado proposed an educational outreach letter to providers to inform providers that buprenorphine use among Medi-Cal fee-for-service beneficiaries is associated with high adherence rates and decreased concomitant use of high-risk medications, including other opioids. Using a two-pronged approach, the letter would either 1) aim to increase the number of Medi-Cal patients receiving treatment with buprenorphine or 2) to increase the number of Medi-Cal providers able to provide buprenorphine treatment. Ms. Fingado stated that for this topic, the confidentiality issues related to drug abuse and treatment make it difficult to do any patient-level educational outreach with providers, so the focus for this outreach is more on the providers themselves.
- An evaluation will be done to identify the top 100 prescribers (by total quantity prescribed) of opioids in the Medi-Cal fee-for-service program. Providers will be ranked by overall total quantity, and then by total quantity of selected opioids between January 1, 2016 and June 30, 2016. These providers will be cross-referenced to the list of California providers with a current waiver to provide buprenorphine treatment. Providers who are among the top prescribers of opioids and who do not currently have a buprenorphine waiver will be sent a letter with more information about buprenorphine training. The mailing will also include the following:
  - Provider's rankings (by total quantity prescribed) of opioid prescribing in the Medi-Cal fee-for-service population
  - Medi-Cal DUR article on buprenorphine
  - Provider response survey
- An additional evaluation will be done to identify the top 100 prescribers (by total number of patients) of buprenorphine in the Medi-Cal program. Providers will be ranked by total number of patients with a paid claim for buprenorphine between July 1, 2015 and June 30, 2016. Providers who are among the top prescribers of buprenorphine will be sent a

letter thanking them for obtaining the waiver and letting them know that the maximum number of patients that qualified providers can treat has been raised to 275. The mailing will also include the following:
    - Medi-Cal DUR article on buprenorphine
    - Provider response survey
- The primary outcome variable will be the percentage increase in the number of patients (all of Medi-Cal) with paid claims for buprenorphine among all providers who received the mailing, calculated one year prior to and one year after the mailing of the letter. Secondary outcome variables will also be assessed after one year and include the number of providers contacted who complete the training and applied for a waiver and the percentage change (by total quantity prescribed) of total opioid prescribing in the Medi-Cal fee-for-service population, by individual provider among providers contacted that were in the Top 100. In addition, prescriber response rates will be calculated, and response data and comments will be presented in aggregate in a report to DHCS and the DUR Board.
- Dr. Mowers commented that prescribers should be excluded who see a lot of patients who might be receiving high doses of pain medication for cancer, sickle-cell anemia, or other similar conditions. Ms. Fingado stated that when calculating the top 100 prescribers, it was possible to exclude claims for patients with cancer. Dr. Albertson stated that he was worried that this would miss other, noncancerous conditions that might require opioids. Dr. Thompson stated that due to data quality issues, she did not suggest relying on the provider specialty information provided within the Medi-Cal Provider Master File. Ms. Fingado stated that because the nature of the letter was not about the quality of opioid prescribing, but rather suggesting the importance of buprenorphine training, it might be acceptable to include all prescribers.

- A motion was made – and seconded – to accept this proposal. There was no further discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendation to conduct an educational outreach to providers regarding buprenorphine training and prescribing will be submitted to DHCS.

i. Policy Impact Report: Antipsychotic TAR Requirement for Children and Adolescents – Ms. Fingado reported that in March 2015, the Drug Use Review (DUR) Program published an educational bulletin entitled, *"Improving the Quality of Care: Antipsychotic Use in Children and Adolescents."* This bulletin used October 1, 2013, through September 30, 2014 as the measurement year and evaluated the following two new measures that had been added to the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) for 2015:

- Metabolic Monitoring for Children and Adolescents on Antipsychotics (APM), which found 37.4% of children and adolescents who have ongoing use of antipsychotic medications had appropriate metabolic testing during the measurement year
- Use of Multiple Concurrent Antipsychotics in Children and Adolescents (APC), which found 5.7% of children and adolescents were taking two or more concurrent antipsychotics for at least 90 days during the measurement year.

Ms. Fingado stated that as of October 1, 2014, any use of antipsychotics for Medi-Cal beneficiaries 0 – 17 years of age now requires an approved TAR and that the objective of this report was to evaluate pharmacy and medical claims data for the year after the TAR requirement was implemented, in order to determine the impact of the policy change on the Medi-Cal fee-for-service population. To account for the transition period while the policy was being implemented, the measurement year for this updated report analyses was calendar year 2015, in order to allow three months for the implementation of the new policy.

Paid pharmacy and medical claims with dates of service between January 1, 2015 and December 31, 2015, were reviewed for all Medi-Cal fee-for-service beneficiaries 1 – 17 years of age who had at least one paid claim for an antipsychotic medication during this time period. To be included in the study population, continuous eligibility in the Medi-Cal fee-for-service program was required between January 1, 2015, and December 31, 2015, to

allow for complete medical and pharmacy claims data.

Ms. Fingado reported that there were a total of 4,281 continuously eligible Medi-Cal fee-for-service beneficiaries between 1 and 17 years of age in the study population and that the demographic makeup of this study population is almost exactly the same as in the original analysis. The study population remains almost 2/3 male (64%, compared with 65% in the previous study population) and almost half of the beneficiaries identify as white/Caucasian race, non-Hispanic ethnicity (48%, compared with 47% in the previous study population).

For the APM calculation, beneficiaries were excluded if they had only one paid claim for an antipsychotic medication during the measurement year (leaving a denominator of 3,717 beneficiaries). The overall APM rate went up slightly, from 37.4% to 38.9%, although the rate of glucose or Hb1AC monitoring (52.0%, down from 52.4% from the previous study population), continues to be much greater than LDL-C or cholesterol monitoring (39.4%, up from 37.9% from the previous study population). While there was a slight improvement of beneficiary lipid testing, there still is an opportunity for outreach to providers, who could raise the metabolic monitoring rate calculated in the HEDIS measure by ordering both tests at the same time.

For the APC calculation, beneficiaries were excluded from this calculation if they had less than 90 days of continuous antipsychotic medication treatment during the measurement year (leaving a denominator of 3,445 beneficiaries). The calculated APC rate of 6.6% of is slightly higher (< 1%) than before the policy change, although this may be a result of the greater overall reduction in the denominator (36% decrease), as compared with the reduction in the numerator (26% decrease).

Dr. Mowers suggested this might be an area where patient-specific letters should be sent regarding use of antipsychotic medications. Ms. Fingado agreed and briefly described the role of the DUR team as a part of the CMS Antipsychotic Drug Use in Children (ADC) Affinity Group and reported that the Affinity Group was encouraged by the initial mailing of the DUR program on metabolic monitoring. She asked the Board to support efforts of the DUR team to expand the educational outreach regarding metabolic monitoring for children and adolescents using antipsychotic medications to additional providers, as guided by California's Affinity Group team.

A motion was made – and seconded – to accept this proposal. There was no further discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendation to conduct an expanded educational outreach to providers regarding metabolic monitoring for children and adolescents using antipsychotic medications will be submitted to DHCS.

j. Retrospective DUR presented by Shalini Lynch, PharmD (UCSF):

i. Review of Retrospective DUR Criteria: HIV Antiretroviral Drugs

- Dr. Lynch reviewed that on January 1, 2014, California expanded the eligibility for Medi-Cal to include low-income adults with incomes at or below 138 percent of the federal poverty line. Between Q4 2013 and Q1 2014, the total population of eligible Medi-Cal beneficiaries increased by 12.9% and during this same time period there was a 69.6% increase in utilizing beneficiaries with at least one paid claim for an antiretroviral medication used to treat or prevent human immunodeficiency virus (HIV) infection. As HIV antiretroviral medications are covered through the Medi-Cal fee-for-service program, the DUR program was asked to review use of these drugs across the entire Medi-Cal population.

  Pharmacy and claims data were reviewed for all Medi-Cal beneficiaries with at least one paid claim for any HIV antiretroviral medication between January 1, 2013, and December 31, 2015. Demographic, clinical, and enrollment data were obtained from a subset of these Medi-Cal beneficiaries that were continuously eligible in the Medi-Cal

program for the duration of the 2014 calendar year.

Dr. Lynch stated that the number of utilizing beneficiaries with a paid claim for an HIV antiretroviral medication increased by 155% in the two years following the Medicaid expansion in California, with a more rapid increase seen in the use of medications newly approved by the FDA. A total of 13,475 Medi-Cal beneficiaries with at least one paid claim for an HIV antiretroviral medication were identified as being continuously-eligible for Medi-Cal throughout 2014. Demographic characteristics for this population were compared, stratified by whether the beneficiary was enrolled in Medi-Cal FFS or a Medi-Cal managed care plan as of December 2014. Dr. Lynch reported that only 10% of continuously-eligible beneficiaries with a paid claim for an HIV antiretroviral medication were enrolled in the Medi-Cal fee-for-service program and they were more likely to be younger and live in Los Angeles County.

Ms. Fingado reported several challenges when reviewing these data for this review. She stated that the medical claims data only includes a primary and secondary diagnostic code, so the majority of these beneficiaries did not have a documented diagnostic code for HIV. Further, the claims data for many of these beneficiaries started in 2014 with the Medicaid expansion, so complete medical history is lacking for many beneficiaries preceding their enrollment into the Medi-Cal program. The delay in Medi-Cal managed care medical claims also means that 2014 calendar year data is not considered complete until the end of 2015. She suggested keeping these concerns about data quality in mind as we move forward thinking about integrating FFS and managed care data in the future.

Dr. Stafford asked if an evaluation had been conducted on the cost of ARV drugs as individual ingredients when compared with the cost of combination therapy. Ms. Fingado stated that the actual drug costs are unknown and we only could compare the reimbursement rates paid to pharmacies. She stated that she was willing to do this evaluation if the Board requested. Dr. Stafford also asked if an evaluation was conducted on prescribing quality to determine whether or not first-line therapies were being initiated by prescribers. Ms. Fingado reported the difficulty of determining prescribing quality among this population, as many of them do not have medical history in either FFS or managed care prior to 2014 and prior treatments are unknown, as well as any clinical information about side effects or laboratory values.

The Board did not request any further evaluation of these data at this time.

k. Review of DUR Publications presented by Dr. Lynch

i. Dr. Lynch summarized the DUR educational bulletin, "*Clinical Review: The Treatment of Opioid Addiction with Buprenorphine,"* which was published in August 2016. The learning objectives were to: 1) review the induction, stabilization, and maintenance phases of the management of opioid addiction; 2) describe strategies for pharmacists and prescribers to promote successful opioid agonist treatment; and 3) summarize best practices for responsible prescribing and dispensing of buprenorphine-containing products.

Dr. Lynch reported that buprenorphine, both by itself and in combination with naloxone, has emerged as a first-line treatment for opioid addiction and as of June 1, 2015, Medi-Cal no longer requires an approved TAR for buprenorphine when prescribed by qualified physicians for treatment of individuals with opioid addiction. She briefly described the three phases of buprenorphine treatment: induction, stabilization, and maintenance.

Dr. Lynch then presented results from a retrospective cohort study that assessed use of buprenorphine, adherence to buprenorphine treatment, and concomitant use of selected medications among all continuously-eligible FFS beneficiaries with at least one paid claim for buprenorphine between June 1, 2015 and May 31, 2016. Adherence was measured by medication possession ratio (MPR).

There were a total of 5,657 beneficiaries meeting inclusion/exclusion for the study population, with almost half of buprenorphine paid claims (46%) for a days' supply less than 30 days. Dr. Lynch reported that as measured by the MPR, a total of 2,628 beneficiaries (47%) had a buprenorphine adherence rate between 80% and 120%, suggesting adherence to buprenorphine maintenance treatment. Of note, Dr. Lynch reported that the 656 beneficiaries with only one paid claim for buprenorphine had a slightly higher rate (5%) of paid claims for other opioids than the study population (3%) or the adherent subgroup (2%) during the measurement year.

Dr. Lynch summarized clinical recommendations for providers and pharmacies, including the following:

- Providers are encouraged to complete 8 hours of training and apply for a waiver to prescribe buprenorphine
- Providers with a waiver should aim to treat their allowed maximum number of patients (can be up as many as 275 patients as of August 8, 2016)
- Pharmacies should ensure that buprenorphine is in stock and available to meet demand for frequent refills and create a safe and welcoming environment

ii. Discussion/Recommendations for Future Educational Bulletins
The calendar for future DUR educational bulletins was reviewed. The Board suggested adding a retrospective DUR review for proton-pump inhibitors. There was no further discussion. The motion was carried.

ACTION ITEM: The DUR Board recommendation to review utilization of proton-pump inhibitors for the February 2017 DUR Board meeting will be submitted to DHCS.

I. Pharmacy Update

i. CMS Update

- Antipsychotic Drug Use in Children (ADC) Affinity Group – Ms. Chan briefly described the goals of the ADC Affinity Group and the role of the DUR program within the group.
- Prescription Opioids Abuse Actions – Ms. Chan stated that on September 29, 2016 there is a CMS teleconference on the topic "Medicaid State Agencies Pharmacy Programs' Latest Strategies to Combat the Opioids Epidemic." At the November DUR Board meeting Ms. Chan will report on this call, which will feature presentations by three states, including California.
- 2018 CMS DUR Annual Report Planning Committee – Ms. Chan reported that some states are testing the feasibility of using the 2015 DUR annual report template for managed care health plans. Effective FFY 2018, managed care health plans will be included in the DUR annual report. CMS is convening a planning committee to seek feedback from state Medicaid programs. California is a member of the planning committee, which will have its first conference call in November 2016.

ii. DHCS Quality Strategy annual update – Ms. Chan reported that this year there is a new web-based QI Evaluation System for the annual survey, in which new questions have been added to address health disparities. Ms. Chan stated that this will allow easier and more efficient updates to existing QI projects and addition of new QI projects. Ms. Chan also reported that there are opportunities to include DUR studies in the DHCS Quality Strategy.

iii. Child Core Set Measures – Ms. Chan discussed the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), which required identification and publishing of a core measure set of children's health care quality measures for voluntary use by State Medicaid and CHIP programs. For 2016 the Measure Applications Partnership (MAP), convened by National Quality Forum (NQF) recommends consideration of up to six new measures for phased addition, including the Use of Multiple Concurrent Antipsychotics in Children & Adolescents (APC).

iv. Adult Core Set Measures – Ms. Chan discussed the new measures in the 2016 Adult Core Set Measures, which measure health care quality for adult Medicaid enrollees. New measures include Diabetes Screening for People with Schizophrenia or Bipolar

	Disorder Who Are Using Antipsychotic Medications (SSD) and the Use of Opioids at High Dosage (OHD). v. Academic Detailing Conference Working Agenda – Ms. Chan reminded the group that the academic detailing conference will be held on October 20, 2016 at DHCS in Sacramento. Clinical topics will include opioids use and misuse, naloxone for opioids overdose, and diabetes, while program topics will include best practices examples, team based care, and developing a business case. The agenda and presentations should be finalized by October 1, 2016.
5) PUBLIC COMMENTS	• Edward Opton, JD, PhD with the National Center for Youth Law made public comments to the Board regarding concerns with the use of psychotropic medications in children and adolescents. Dr. Opton reported that the decision to use or not use medications is often a function of risk, and that the risks for these medications may not be evident until after long-term use is established. He described the recent state auditor's report that called for action by DHCS. The report found that the state and counties have not had oversight of use of psychotropic medications in foster children. Dr. Opton recommends that DHCS implement policies and processes regarding TAR approval for off-label use of psychotropic medications. He states that the current TAR policy allows off-label use for "reasonable" practice and that the definition of "reasonable" is unclear.
6) CONSENT AGENDA	• The next Board meeting will be held from 9:30 a.m. to 12:30 p.m. on November 15, 2016 in DHCS Training Rooms B+C located at 1500 Capitol Avenue, Sacramento, CA 95814.
7) ADJOURNMENT	• The meeting was adjourned at 12:37 p.m.

Action Items	**Ownership**
Incorporate Dr. Wong's edits into the minutes and post to the DUR website.	Amanda
The DUR Board recommendation to evaluate replacing the current policy of a maximum of three dispensings of opioids within any 75-day period to a maximum supply of 30 days will be submitted to DHCS.	Pauline/Amanda
The DUR Board recommendation to have a DUR Board member participate in the state opioid workgroup will be submitted to DHCS.	Pauline
The DUR Board recommendation to approve and submit the FFY 2015 DUR Annual Report to CMS will be submitted to DHCS.	Pauline/Amanda
The DUR Board recommendation to conduct an educational outreach to providers regarding asthma quality-of-care will be submitted to DHCS.	Amanda
The DUR Board recommendation to conduct an educational outreach to providers regarding buprenorphine training and prescribing will be submitted to DHCS.	Amanda
The DUR Board recommendation to conduct an expanded educational outreach to providers regarding metabolic monitoring for children and adolescents using antipsychotic medications will be submitted to DHCS.	Amanda
The DUR Board recommendation to review utilization of proton-pump inhibitors for the February 2017 DUR Board meeting will be submitted to DHCS.	Amanda

QUARTERLY SUMMARY
DRUG USE REVIEW (DUR) UTILIZATION REVIEW
REPORT PERIOD: 3rd QUARTER 2016 (JULY - SEPTEMBER 2016)

Executive Summary

The DUR quarterly report provides information on both prospective and retrospective drug utilization for the Medi-Cal Fee-for-Service (FFS) program. For this quarterly report, the prospective and retrospective data cover the third quarter of 2016 (2016 Q3). All tables can be found in **Appendix A** and definitions of selected terms can be found in **Appendix B**.

Prospective DUR

As shown in Table 1.1, in comparison to the prior quarter (2016 Q2), in 2016 Q3 overall drug claims decreased by 6% and total DUR alerts decreased by 10%. In comparison to the prior-year quarter (2015 Q3), overall drug claims decreased by 7% and total DUR alerts decreased by 3%.

A comparison between 2016 Q3 and 2016 Q2 showed very little change among the summary of alert transactions by therapeutic problem (**Table 1.2**) and among the top 10 drugs for each of the 12 prospective DUR alerts (**Tables 2.1-2.12**).

Retrospective DUR

A comparison of 2016 Q3 to both the prior quarter and the prior-year quarter showed an across-the-board decrease in total utilizing beneficiaries and total paid claims (**Table 3**).

As shown in **Table 4**, the greatest decrease in utilizing beneficiaries in comparison to both the prior quarter and the prior-year quarter was in the 12 years and under age group, which posted a decrease of 11% from the prior quarter and a decrease of 15% from the prior-year quarter.

As shown in **Table 5**, none of the top 20 drug therapeutic categories posted across-the-board increases in total paid claims and percent of utilizing beneficiaries with a paid claim in comparison to both the prior quarter and the prior-year quarter, while eleven drug therapeutic categories posted double-digit percentage decreases in total paid claims for both the prior quarter and the prior-year quarter.

Similar findings can be seen in **Table 6**, where only LURASIDONE posted across-the-board increases in total paid claims and percent of utilizing beneficiaries with a paid claim in comparison to both the prior quarter and the prior-year quarter. The following four drugs posted double-digit percentage decreases in total paid claims for both the prior quarter and the prior-year quarter: IBUPROFEN, AMOXICILLIN, ALBUTEROL SULFATE, and LISINOPRIL.

Finally, each year in the Q3 report we provide the annual utilization summary of drugs by sourcing status that will be included in the annual report (**Table 7.1**). For reference, **Table 7.2** presents the top 10 drugs in each source code category, by total utilizing beneficiaries. Source status is determined through National Drug Code (NDC). Across all three categories the top NDC codes by total utilizing beneficiaries in the Federal fiscal year 2016 (FFY 2016) were almost identical to the previous year (FFY 2015).

Appendix A: Prospective and Retrospective DUR Tables

Tables 1.1-1.2. Summary of Prospective DUR Alert Transactions.

Table 1.1 provides summary level data (by volume) on pharmacy claims and DUR alert activities, including data and percent change from the prior quarter and prior-year quarter. Alerts are generated after adjudication of drug claims that exceed or otherwise fall outside of certain prescribed parameters. Please see **Appendix B** for definitions of terms used in this DUR report.

Table 1.1: Summary of Alert Transactions					
Category	Current Quarter 2016 Q3 (Jul – Sep 2016)	Prior Quarter 2016 Q2 (Apr – Jun 2016)	% Change from *Prior Quarter*	Prior-Year Quarter 2015 Q3 (Jul – Sep 2015)	% Change from *Prior-Year Quarter*
Drug Claims	8,281,627	8,833,238	**-6.2%**	8,914,602	**-7.1%**
DUR Drug Claims	4,121,197	4,548,064	**-9.4%**	4,609,954	**-10.6%**
Total Alerts	990,135	1,098,094	**-9.8%**	1,017,641	**-2.7%**
Total Alert Overrides	583,135	638,792	**-8.7%**	589,846	**-1.1%**
Total Alert Cancels	218	292	**-25.3%**	180	**21.1%**

Note: Drug claims receiving multiple alerts can be adjudicated by pharmacists by responding to only one conflict code, followed by an intervention code and outcome code. The remaining alerts on the claim cannot be tracked as they are overridden by the pharmacist's response to a single alert. For example, a single claim can generate up to eight different alerts, but the pharmacist can override all eight alerts by choosing to override only one alert. In addition, the number of cancelled alerts may be underrepresented due to the system's inability to capture claims that were not adjudicated.

Table 1.2 provides a summary of the number of drug claims and alerts generated for each therapeutic problem type (sorted by alert frequency). Total alerts not adjudicated may be overrepresented, as claims with multiple alerts that have been adjudicated under one alert will show up as not adjudicated for the remaining alerts.

Table 1.2: Summary of Alert Transactions by Therapeutic Problem Type – 2016 Q3							
Therapeutic Problem Type	Total Alerts	Total Alert Over-rides	% Alert Over-rides	Total Alert Cancels	% Alert Cancels	Total Alerts Not Adjud-icated	% Alerts Not Adjud-icated
Early Refill (ER)	304,555	94,869	31.2%	102	0.0%	209,584	68.8%
Ingredient Duplication (ID)	215,677	151,735	70.4%	28	0.0%	63,914	29.6%
Therapeutic Duplication (TD)	188,009	135,021	71.8%	33	0.0%	52,955	28.2%
Late Refill (LR)	123,440	93,321	75.6%	29	0.0%	30,090	24.4%
Total High Dose (HD)	52,488	32,135	61.2%	3	0.0%	20,350	38.8%
Additive Toxicity (AT)	39,426	30,829	78.2%	18	0.0%	8,579	21.8%
Total Low Dose (LD)	26,722	16,771	62.8%	2	0.0%	9,949	37.2%
Drug-Pregnancy (PG)	26,221	18,447	70.4%	3	0.0%	7,771	29.6%
Drug-Drug (DD)	10,264	7,705	75.1%	0	0.0%	2,559	24.9%
Drug-Disease (MC)	3,052	2,130	69.8%	0	0.0%	922	30.2%
Drug-Allergy (DA)	232	138	59.5%	0	0.0%	94	40.5%
Drug-Age (PA)	49	34	69.4%	0	0.0%	15	30.6%

Tables 2.1-2.12. Prospective DUR Alert Transactions by Therapeutic Problem Type.

Each of the following tables provides greater detail of each of the 12 DUR alerts with the top 10 drugs generating each respective alert. For each of the top 10 drugs, data are provided for the total number of adjudicated alerts, alert overrides, alert cancels, paid claims, and the percentage of paid claims with alert overrides. **Tables are listed in order of DUR alert priority, which is determined by the DUR Board.**

Table 2.1: Top 10 Drugs by Therapeutic Problem Type – Drug-Allergy (DA) – 2016 Q3

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	PHENYTOIN SODIUM EXTENDED	94	94	0	2,692	3.5%
2	PHENYTOIN	68	68	0	996	6.8%
3	AMOXICILLIN	7	7	0	38,043	0.0%
4	IBUPROFEN	6	6	0	90,522	0.0%
5	AMOXICILLIN/POTASSIUM CLAV	5	5	0	9,400	0.1%
6	OXYCODONE HCL/ACETAMINOPHEN	4	4	0	7,452	0.1%
7	LORATADINE	2	2	0	46,872	0.0%
8	ASPIRIN	1	1	0	75,146	0.0%
9	BACLOFEN	1	1	0	14,336	0.0%
10	ERYTHROMYCIN BASE	1	1	0	4,209	0.0%

Table 2.2: Top 10 Drugs by Therapeutic Problem Type – Drug-Pregnancy (PG) – 2016 Q3

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	IBUPROFEN	15,932	15,929	3	90,522	17.6%
2	NORETHINDRONE	2,882	2,882	0	8,417	34.2%
3	SULFAMETHOXAZOLE/TRIMETHOPRIM	606	606	0	20,802	2.9%
4	ASPIRIN	595	595	0	75,146	0.8%
5	DOXYCYCLINE HYCLATE	337	337	0	5,517	6.1%
6	NAPROXEN	328	328	0	14,097	2.3%
7	METHYLERGONOVINE MALEATE	308	307	1	246	124.8%
8	MISOPROSTOL	277	277	0	725	38.2%
9	LORAZEPAM	180	180	0	12,255	1.5%
10	LISINOPRIL	129	129	0	34,516	0.4%

Table 2.3: Top 10 Drugs by Therapeutic Problem Type – Drug-Disease (MC) – 2016 Q3

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	POTASSIUM CHLORIDE	673	673	0	4,077	16.5%
2	METFORMIN HCL	407	407	0	42,642	1.0%
3	HALOPERIDOL	404	404	0	21,266	1.9%
4	CARBAMAZEPINE	82	82	0	4,005	2.0%
5	METOPROLOL TARTRATE	77	77	0	9,105	0.8%
6	METOPROLOL SUCCINATE	74	74	0	5,540	1.3%
7	ATENOLOL	72	72	0	7,150	1.0%
8	HALOPERIDOL DECANOATE	62	62	0	3,842	1.6%
9	SOMATROPIN	57	57	0	2,167	2.6%
10	PROPRANOLOL HCL	53	53	0	4,503	1.2%

Table 2.4: Top 10 Drugs by Therapeutic Problem Type – Drug-Drug Interaction (DD) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	GEMFIBROZIL	654	654	0	3,141	20.8%
2	SIMVASTATIN	542	542	0	14,105	3.8%
3	ELVITEG/COBI/EMTRIC/TENOFO ALA	471	471	0	7,300	6.5%
4	ATORVASTATIN CALCIUM	390	390	0	24,823	1.6%
5	METOCLOPRAMIDE HCL	382	382	0	5,841	6.5%
6	DARUNAVIR ETHANOLATE	336	336	0	6,995	4.8%
7	AMLODIPINE BESYLATE	312	312	0	23,099	1.4%
8	ZIPRASIDONE HCL	236	236	0	20,124	1.2%
9	ELVITEG/COBI/EMTRIC/TENOFO DIS	209	209	0	4,573	4.6%
10	DARUNAVIR/COBICISTAT	188	188	0	3,980	4.7%

Table 2.5: Top 10 Drugs by Therapeutic Problem Type – Therapeutic Duplication (TD) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	24,712	24,709	3	136,922	18.0%
2	OLANZAPINE	15,905	15,901	4	73,007	21.8%
3	RISPERIDONE	15,078	15,076	2	87,303	17.3%
4	LURASIDONE HCL	9,220	9,218	2	35,872	25.7%
5	CLOZAPINE	6,126	6,124	2	18,404	33.3%
6	TRAZODONE HCL	5,750	5,748	2	12,218	47.0%
7	PALIPERIDONE PALMITATE	5,496	5,496	0	14,915	36.8%
8	ZIPRASIDONE HCL	5,034	5,034	0	20,124	25.0%
9	ALBUTEROL SULFATE	4,285	4,285	0	42,963	10.0%
10	BUPROPION HCL	4,023	4,023	0	7,173	56.1%

Table 2.6: Top 10 Drugs by Therapeutic Problem Type – Overutilization (ER) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	9,470	9,462	8	136,922	6.9%
2	ARIPIPRAZOLE	7,944	7,942	2	102,321	7.8%
3	RISPERIDONE	5,456	5,453	3	87,303	6.2%
4	OLANZAPINE	5,034	5,033	1	73,007	6.9%
5	BENZTROPINE MESYLATE	4,475	4,474	1	57,176	7.8%
6	LITHIUM CARBONATE	2,744	2,743	1	30,025	9.1%
7	ASPIRIN	2,387	2,385	2	75,146	3.2%
8	METFORMIN HCL	2,028	2,026	2	42,642	4.8%
9	LURASIDONE HCL	2,021	2,019	2	35,872	5.6%
10	LISINOPRIL	1,761	1,761	0	34,516	5.1%

Table 2.7: Top 10 Drugs by Therapeutic Problem Type – Underutilization (LR) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	ARIPIPRAZOLE	18,729	18,722	7	102,321	18.3%
2	QUETIAPINE FUMARATE	17,492	17,488	4	136,922	12.8%
3	RISPERIDONE	10,893	10,892	1	87,303	12.5%
4	OLANZAPINE	8,144	8,142	2	73,007	11.2%
5	BENZTROPINE MESYLATE	7,319	7,317	2	57,176	12.8%
6	LURASIDONE HCL	5,338	5,337	1	35,872	14.9%
7	LITHIUM CARBONATE	4,488	4,488	0	30,025	14.9%
8	LEVOTHYROXINE SODIUM	3,368	3,366	2	28,139	12.0%
9	ATORVASTATIN CALCIUM	2,795	2,795	0	24,823	11.3%
10	HALOPERIDOL	2,662	2,662	0	21,266	12.5%

Table 2.8: Top 10 Drugs by Therapeutic Problem Type – Additive Toxicity (AT) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	ARIPIPRAZOLE	1,967	1,967	0	102,321	1.9%
2	QUETIAPINE FUMARATE	1,843	1,842	1	136,922	1.3%
3	LITHIUM CARBONATE	1,554	1,554	0	30,025	5.2%
4	CLONAZEPAM	1,396	1,393	3	8,701	16.0%
5	HALOPERIDOL	1,161	1,161	0	21,266	5.5%
6	OLANZAPINE	1,060	1,060	0	73,007	1.5%
7	ZOLPIDEM TARTRATE	806	806	0	5,073	15.9%
8	RISPERIDONE	661	661	0	87,303	0.8%
9	TRAZODONE HCL	660	660	0	12,218	5.4%
10	CHLORPROMAZINE HCL	575	574	1	6,097	9.4%

Table 2.9: Top 10 Drugs by Therapeutic Problem Type – Ingredient Duplication (ID) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	28,721	28,721	0	136,922	21.0%
2	OLANZAPINE	14,416	14,412	4	73,007	19.7%
3	ARIPIPRAZOLE	14,221	14,219	2	102,321	13.9%
4	RISPERIDONE	12,027	12,022	5	87,303	13.8%
5	CLOZAPINE	5,829	5,829	0	18,404	31.7%
6	LURASIDONE HCL	5,255	5,254	1	35,872	14.6%
7	ALBUTEROL SULFATE	5,007	5,006	1	42,963	11.7%
8	ZIPRASIDONE HCL	4,106	4,105	1	20,124	20.4%
9	HALOPERIDOL	3,557	3,556	1	21,266	16.7%
10	LEVOTHYROXINE SODIUM	3,002	3,002	0	28,139	10.7%

Table 2.10: Top 10 Drugs by Therapeutic Problem Type – Drug-Age (PA) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	AMITRIPTYLINE HCL	28	28	0	3,861	0.7%
2	BUDESONIDE	9	9	0	4,194	0.2%
3	LORATADINE	8	8	0	46,872	0.0%
4	CAPECITABINE	6	6	0	348	1.7%
5	DOXEPIN HCL	6	6	0	407	1.5%
6	MYCOPHENOLATE MOFETIL	6	6	0	2,919	0.2%
7	RISPERIDONE	6	6	0	87,303	0.0%
8	ENOXAPARIN SODIUM	5	5	0	1,681	0.3%
9	LATANOPROST	5	5	0	312	1.6%
10	TRIHEXYPHENIDYL HCL	4	4	0	5,692	0.1%

Table 2.11: Top 10 Drugs by Therapeutic Problem Type – High Dose (HD) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	OLANZAPINE	8,183	8,182	1	73,007	11.2%
2	RISPERIDONE	2,931	2,930	1	87,303	3.4%
3	QUETIAPINE FUMARATE	2,430	2,430	0	136,922	1.8%
4	HYDROCODONE/ACETAMINOPHEN	2,228	2,228	0	44,863	5.0%
5	IBUPROFEN	1,411	1,411	0	90,522	1.6%
6	GABAPENTIN	1,296	1,296	0	23,089	5.6%
7	ARIPIPRAZOLE	1,095	1,095	0	102,321	1.1%
8	AMOXICILLIN	865	865	0	38,043	2.3%
9	ZIPRASIDONE HCL	793	793	0	20,124	3.9%
10	AMOXICILLIN/POTASSIUM CLAV	756	756	0	9,400	8.0%

Table 2.12: Top 10 Drugs by Therapeutic Problem Type – Low Dose (LD) – 2016 Q3						
Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	LITHIUM CARBONATE	4,703	4,703	0	30,025	15.7%
2	GABAPENTIN	1,895	1,895	0	23,089	8.2%
3	AZITHROMYCIN	705	704	1	21,179	3.3%
4	CLONIDINE HCL	652	652	0	9,837	6.6%
5	AMOXICILLIN	612	612	0	38,043	1.6%
6	DIVALPROEX SODIUM	596	596	0	13,053	4.6%
7	ERYTHROMYCIN ETHYLSUCCINATE	557	557	0	1,703	32.7%
8	CEPHALEXIN	488	488	0	29,172	1.7%
9	AMOXICILLIN/POTASSIUM CLAV	453	453	0	9,400	4.8%
10	METHYLPHENIDATE HCL	413	413	0	5,667	7.3%

Table 3. Summary of Medi-Cal FFS Pharmacy / Drug Utilization Measures.

This table shows pharmacy utilization for the Medi-Cal FFS population, including the percent change from the prior quarter and prior-year quarter. Please note that all retrospective data tables exclude claims from beneficiaries in the Family Planning, Access, Care, and Treatment (Family PACT) program and the California Children's Services/ Genetically Handicapped Persons Program (CCS/GHPP) because they have different guidelines concerning access to prescription drugs than other Medi-Cal FFS beneficiaries.

Table 3: Pharmacy Utilization Measures for the Medi-Cal FFS Population					
Category	**Current Quarter 2016 Q3**	**Prior Quarter 2016 Q2**	**Prior-Year Quarter 2015 Q3**	**% Change from *Prior Quarter***	**% Change from *Prior-Year Quarter***
Total Eligible FFS Beneficiaries	2,488,808	2,697,522	2,677,146	**-7.7%**	**-7.0%**
Total Utilizing FFS Beneficiaries	772,130	818,051	825,458	**-5.6%**	**-6.5%**
Total Paid Rx Claims	2,607,270	2,853,608	2,901,528	**-8.6%**	**-10.1%**
Average Paid Rx Claims per Eligible FFS Beneficiary	1.05	1.06	1.08	**-1.2%**	**-3.0%**
Average Paid Rx Claims per Utilizing FFS Beneficiary	3.38	3.49	3.52	**-3.2%**	**-4.1%**
Total Reimbursement Paid ($) to Pharmacies	$573,733,431	$629,661,657	$715,478,731	**-8.9%**	**-19.8%**
Average Reimbursement Paid ($) per Eligible FFS Beneficiary	$230.53	$233.42	$267.25	**-1.2%**	**-13.7%**
Average Reimbursement Paid ($) per Utilizing FFS Beneficiary	$743.05	$769.71	$866.77	**-3.5%**	**-14.3%**
Average Reimbursement Paid ($) per Paid Rx Claim	$220.05	$220.65	$246.59	**-0.3%**	**-10.8%**

Table 4. Pharmacy Utilization by Age Group in the Medi-Cal FFS Population.

This table presents pharmacy utilization data broken out by age group, including the percent change from the prior quarter and prior-year quarter.

Table 4: Pharmacy Utilization by Age Group in the Medi-Cal FFS Population						
Age Group (years)	**Current Quarter 2016 Q3 Total Paid Claims**	**% Change Total Paid Claims from *Prior Quarter***	**% Change Total Paid Claims from *Prior-Year Quarter***	**Current Quarter 2016 Q3 Total Utilizing Beneficiaries**	**% Change Total Utilizing Beneficiaries from *Prior Quarter***	**% Change Total Utilizing Beneficiaries from *Prior-Year Quarter***
0 – 12	223,223	**-13.9%**	**-14.2%**	97,345	**-11.4%**	**-14.5%**
13 – 18	130,832	**-5.1%**	**-11.0%**	41,570	**-3.5%**	**-10.6%**
19 – 39	794,779	**-7.8%**	**-8.2%**	255,443	**-5.9%**	**-5.6%**
40 – 64	1,182,440	**-7.8%**	**-10.1%**	284,073	**-3.8%**	**-3.3%**
65+	258,028	**-12.0%**	**-10.6%**	86,165	**-5.2%**	**-4.9%**
Total*	2,607,270	**-8.6%**	**-10.1%**	772,130	**-5.6%**	**-6.5%**

* Unknowns represent less than 1% of total

Table 5. Top 20 Drug Therapeutic Categories in the Medi-Cal FFS Population.

This table presents utilization of the top 20 drug therapeutic categories, by **percentage of utilizing beneficiaries with a paid claim.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization and reimbursement dollars paid to pharmacies for these top utilized drugs. The prior-year quarter ranking of the drug therapeutic category is listed for reference.

Table 5: Top 20 Drug Therapeutic Categories by *Percentage of Utilizing Beneficiaries with a Paid Claim*

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2016 Q3 Total Paid Claims	% Change Total Paid Claims from *Prior Quarter*	% Change Total Paid Claims from *Prior-Year Quarter*	Current Quarter 2016 Q3 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Utilizing Beneficiaries with a Paid Claim from *Prior Quarter*	% Change Utilizing Beneficiaries with a Paid Claim from *Prior-Year Quarter*
1	1	ANTIPSYCHOTIC,ATYPICAL,DOPAMINE,SEROTONIN ANTAGNST	398,711	-0.9%	0.1%	136,724	17.7%	0.8%	1.3%
2	2	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	110,827	-12.3%	-12.5%	95,831	12.4%	-0.8%	-0.8%
3	3	NARCOTIC ANALGESIC AND NON-SALICYLATE ANALGESIC	64,062	-9.5%	-21.9%	50,672	6.6%	-0.2%	-1.1%
4	5	ANALGESIC/ANTIPYRETICS, SALICYLATES	74,196	-4.8%	-6.6%	49,089	6.4%	0.1%	0.0%
5	4	PENICILLINS	52,140	-19.7%	-16.4%	47,508	6.2%	-1.1%	-0.7%
6	6	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	104,593	-1.3%	3.1%	45,281	5.9%	0.2%	0.5%
7	7	LAXATIVES AND CATHARTICS	55,610	-4.5%	-12.7%	37,062	4.8%	0.0%	-0.4%
8	8	IRON REPLACEMENT	44,933	-7.0%	-7.3%	34,112	4.4%	-0.2%	-0.2%
9	9	ANTICONVULSANTS	84,513	-10.0%	-12.4%	33,911	4.4%	0.0%	-0.1%
10	10	ANTIHYPERTENSIVES, ACE INHIBITORS	46,146	-13.6%	-16.1%	30,718	4.0%	-0.2%	-0.3%
11	11	ANTIHISTAMINES - 2ND GENERATION	46,886	-16.2%	-6.9%	30,692	4.0%	-0.6%	0.0%
12	14	ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	45,723	-14.6%	-10.1%	30,058	3.9%	-0.3%	0.0%
13	13	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	39,065	-17.0%	-15.0%	28,149	3.6%	-0.5%	-0.3%
14	17	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	40,475	-10.9%	-8.0%	27,178	3.5%	-0.1%	0.0%
15	16	CEPHALOSPORINS - 1ST GENERATION	27,670	-4.1%	-12.7%	26,047	3.4%	0.0%	-0.2%
16	12	PRENATAL VITAMIN PREPARATIONS	28,816	-10.1%	-24.2%	25,471	3.3%	-0.3%	-0.7%
17	19	ANTIPARKINSONISM DRUGS,ANTICHOLINERGIC	62,708	-1.8%	-3.8%	24,977	3.2%	0.1%	0.1%
18	15	TOPICAL ANTI-INFLAMMATORY STEROIDAL	29,835	-10.7%	-19.8%	24,604	3.2%	-0.3%	-0.4%
19	18	ANTIHISTAMINES - 1ST GENERATION	32,664	-10.5%	-13.4%	23,156	3.0%	-0.1%	-0.2%
20	21	SELECTIVE SEROTONIN REUPTAKE INHIBITOR (SSRIS)	40,324	-11.6%	-13.7%	22,912	3.0%	-0.1%	-0.1%

Table 6. Top 20 Drugs in the Medi-Cal FFS Population.

This table presents utilization of the top 20 drugs, by **percentage of utilizing beneficiaries with a paid claim.** The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of each drug is listed for reference.

Utilization of drugs for Medi-Cal fee-for-service beneficiaries also includes carved-out drugs utilized by beneficiaries in Medi-Cal managed care plans. Carved-out drugs are listed below in bolded and italicized print.

Table 6: Top 20 Drugs by *Percentage of Utilizing Beneficiaries with a Paid Claim*

Rank	Last Year Rank	Drug Description	Current Quarter 2016 Q3 Total Paid Claims	% Change Total Paid Claims from *Prior Quarter*	% Change Total Paid Claims from *Prior-Year Quarter*	Current Quarter 2016 Q3 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change of Utilizing Beneficiaries with a Paid Claim from *Prior Quarter*	% Change of Utilizing Beneficiaries with a Paid Claim from *Prior-Year Quarter*
1	1	IBUPROFEN	89,975	-12.3%	-12.6%	80,360	10.4%	-0.7%	-0.7%
2	***3***	***QUETIAPINE FUMARATE***	***136,770***	***-1.0%***	***1.7%***	***53,062***	***6.9%***	***0.3%***	***0.6%***
3	2	ASPIRIN	74,159	-4.8%	-6.3%	49,057	6.4%	0.1%	0.0%
4	***5***	***ARIPIPRAZOLE***	***102,097***	***-1.9%***	***0.6%***	***44,341***	***5.7%***	***0.2%***	***0.4%***
5	4	HYDROCODONE/ ACETAMINOPHEN	44,252	-7.2%	-20.2%	36,001	4.7%	0.0%	-0.7%
6	7	DOCUSATE SODIUM	52,371	-4.0%	-11.4%	35,597	4.6%	0.1%	-0.3%
7	***8***	***RISPERIDONE***	***86,544***	***-1.9%***	***-6.3%***	***35,063***	***4.5%***	***0.2%***	***0.0%***
8	6	AMOXICILLIN	37,546	-20.4%	-15.7%	34,770	4.5%	-0.8%	-0.5%
9	9	FERROUS SULFATE	44,887	-7.0%	-5.7%	34,087	4.4%	-0.1%	-0.1%
10	11	LORATADINE	46,351	-16.2%	-6.7%	30,433	3.9%	-0.6%	0.0%
11	10	ALBUTEROL SULFATE	39,792	-17.2%	-14.9%	28,881	3.7%	-0.5%	-0.3%
12	***14***	***OLANZAPINE***	***72,938***	***-0.2%***	***5.0%***	***27,987***	***3.6%***	***0.2%***	***0.5%***
13	13	METFORMIN HCL	40,475	-10.9%	-7.8%	27,178	3.5%	-0.1%	0.0%
14	12	CEPHALEXIN	27,638	-4.1%	-12.5%	26,031	3.4%	0.1%	-0.2%
15	***17***	***BENZTROPINE MESYLATE***	***57,161***	***-1.7%***	***-2.9%***	***22,865***	***3.0%***	***0.1%***	***0.1%***
16	16	LISINOPRIL	33,541	-12.3%	-12.8%	22,500	2.9%	-0.1%	-0.1%
17	15	ACETAMINOPHEN	22,825	-9.9%	-16.7%	21,451	2.8%	-0.1%	-0.3%
18	18	FOLIC ACID	32,632	-5.3%	-9.2%	19,046	2.5%	0.0%	-0.2%
19	32	ATORVASTATIN CALCIUM	24,577	-9.9%	14.4%	16,167	2.1%	0.0%	0.5%
20	***29***	***LURASIDONE HCL***	***35,862***	***0.9%***	***7.2%***	***15,543***	***2.0%***	***0.1%***	***0.3%***

Tables 7.1-7.2. Summary of Generic Drug Utilization – FFY 2016 (October 1, 2015-September 30, 2016).

The Centers for Medicare & Medicaid Services (CMS) developed an extract file from the Medicaid Drug Rebate Program Drug Product Data File identifying each National Drug Code (NDC) along with sourcing status: S, N, or I (see key below). This file was made available from CMS to facilitate consistent reporting and contains the active drugs that have been reported by participating manufacturers as of the most recent rebate reporting period under the Medicaid Drug Rebate Program. **Table 7.1** presents a utilization summary of drugs by sourcing status over the last Federal Fiscal Year (FFY), with the current FFY compared to the previous FFY in order to show any changes in utilization. **Table 7.2** presents the top 10 drugs in each source code category, by total utilizing beneficiaries.

Table 7.1: Drug Utilization by Source Code – FFY 2016

Single-Source (S) Drugs			Non-Innovator (N) Drugs			Innovator Multi-Source (I) Drugs		
Total Number of Claims	% Change Total Number of Claims from *Prior Year*	Total Reimburse-ment Amount Less Co-Pay	Total Number of Claims	% Change Total Number of Claims from *Prior Year*	Total Reimburse-ment Amount Less Co-Pay	Total Number of Claims	% Change Total Number of Claims from *Prior Year*	Total Reimburse-ment Amount Less Co-Pay
1,997,802	**-7.6%**	$2,336,885,404	8,479,011	**-4.9%**	$327,116,716	1,661,427	**-22.3%**	$886,674,253

- Single-Source (S) - Drugs that have an FDA New Drug Application (NDA) approval for which there are no generic alternatives available on the market
- Non-Innovator Multiple-Source (N) - Drugs that have an FDA Abbreviated New Drug Application (ANDA) approval and for which there exists generic alternatives on the market
- Innovator Multiple-Source (I) - Drugs which have an NDA and no longer have patent exclusivity

Table 7.2. Top 10 Drugs in each Source Code by Total Utilizing Beneficiaries – FFY 2016

Single-Source (S) - Drugs that have an FDA New Drug Application (NDA) approval for which there are no generic alternatives available on the market

NDC	Drug Description	Product Label Name	Total Reimbursement Dollars Paid to Pharmacies	Total Utilizing Beneficiaries	Total Paid Claims
59310057922	ALBUTEROL SULFATE	PROAIR HFA 90 MCG INHALER	$9,238,824	95,679	148,098
00088222033	INSULIN GLARGINE,HUM.REC.ANLOG	LANTUS 100 UNITS/ML VIAL	$27,716,215	22,378	79,361
00085128801	MOMETASONE FUROATE	NASONEX 50 MCG NASAL SPRAY	$6,217,686	18,306	27,668
00186504031	ESOMEPRAZOLE MAGNESIUM	NEXIUM DR 40 MG CAPSULE	$12,815,586	15,864	40,217
00052027303	ETONOGESTREL/ETHINYL ESTRADIOL	NUVARING VAGINAL RING	$10,592,971	15,774	35,641
00430042014	NORETHINDRONE-E.ESTRADIOL-IRON	LO LOESTRIN FE 1-10 TABLET	$8,724,683	15,739	34,286
61958070101	EMTRICITABINE/TENOFOVIR	TRUVADA 200 MG-300 MG TABLET	$120,338,004	14,104	86,724
00002751001	INSULIN LISPRO	HUMALOG 100 UNITS/ML VIAL	$20,085,945	13,594	50,260
63402030430	LURASIDONE HCL	LATUDA 40 MG TABLET	$42,024,020	13,261	42,452
00085113201	ALBUTEROL SULFATE	PROVENTIL HFA 90 MCG INHALER	$1,195,535	11,606	16,333

Non-Innovator Multiple-Source (N) - Drugs that have an FDA Abbreviated New Drug Application (ANDA) approval and for which there exists generic alternatives on the market

NDC	Drug Description	Product Label Name	Total Reimbursement Dollars Paid to Pharmacies	Total Utilizing Beneficiaries	Total Paid Claims
00603002632	ASPIRIN	ASPIRIN EC 81 MG TABLET	$1,226,755	53,983	159,433
55111068305	IBUPROFEN	IBUPROFEN 600 MG TABLET	$456,118	49,388	56,931
45802065087	LORATADINE	LORATADINE 10 MG TABLET	$976,250	42,243	104,435
00603158658	D-METHORPHAN HB/PROMETH HCL	PROMETHAZINE-DM SYRUP	$775,729	42,077	59,150
00406012301	HYDROCODONE BIT/ACETAMINOPHEN	HYDROCODON-ACETAMINOPHEN 5-325	$660,701	38,312	46,930
69238110205	IBUPROFEN	IBUPROFEN 600 MG TABLET	$341,046	36,662	41,584
00603015021	DOCUSATE SODIUM	DOC-Q-LACE 100 MG SOFTGEL	$520,954	34,739	55,141
00603389021	HYDROCODONE BIT/ACETAMINOPHEN	HYDROCODON-ACETAMINOPHEN 5-325	$591,910	34,147	39,995
00591320205	HYDROCODONE BIT/ACETAMINOPHEN	HYDROCODON-ACETAMINOPHEN 5-325	$621,494	33,947	42,697
68180012202	CEPHALEXIN	CEPHALEXIN 500 MG CAPSULE	$404,141	33,703	36,951

Innovator Multiple-Source (I) - Drugs which have an NDA and no longer have patent exclusivity

NDC	Drug Description	Product Label Name	Total Reimbursement Dollars Paid to Pharmacies	Total Utilizing Beneficiaries	Total Paid Claims
59148000713	ARIPIPRAZOLE	ABILIFY 5 MG TABLET	$102,192,735	27,774	103,280
59148000813	ARIPIPRAZOLE	ABILIFY 10 MG TABLET	$88,737,415	24,324	91,497
00310027110	QUETIAPINE FUMARATE	SEROQUEL 100 MG TABLET	$20,764,349	21,609	71,504
00310027510	QUETIAPINE FUMARATE	SEROQUEL 25 MG TABLET	$15,218,738	20,434	63,686
47781030301	NITROFURANTOIN MONOHYD/ M-CRYST	NITROFURANTOIN MONO-MCR 100 MG	$630,720	15,364	17,142
59148000913	ARIPIPRAZOLE	ABILIFY 15 MG TABLET	$53,946,982	13,790	56,945
00002411730	OLANZAPINE	ZYPREXA 10 MG TABLET	$29,360,501	13,515	44,644
00310027210	QUETIAPINE FUMARATE	SEROQUEL 200 MG TABLET	$25,020,316	12,710	45,435
50458025115	NORGESTIMATE-ETHINYL ESTRADIOL	ORTHO TRI-CYCLEN LO TABLET	$5,943,301	11,354	18,621
59148000613	ARIPIPRAZOLE	ABILIFY 2 MG TABLET	$38,730,150	10,765	39,295

APPENDIX B: Definition of terms.

Adjudicate: To pay or deny drug claims after evaluating the claim for coverage requirements

Average Reimbursement ($): A measure of the mean value of the reimbursement in dollars; the sum of the reimbursement divided by the number measured (in dollars).

Beneficiary: A person who has been determined eligible for Medi-Cal, as according to the California Code of Regulations 50024

Eligible FFS beneficiary: A Medi-Cal FFS beneficiary that qualifies for drug benefits

Quarter: One fourth, ¼, 25% or .25 of a year measured in months.

Reimbursement: The reimbursement paid to Medi-Cal pharmacy providers for legend and nonlegend drugs dispensed to Medi-Cal Fee-for-Service (FFS) beneficiaries. Reimbursement is determined in accordance with CA Welfare and Institutions Code Section 14105.45(b)(1).

Drug therapeutic category: Drug therapeutic categories are grouping of drugs at various hierarchy levels and characteristics that may be similar in chemical structure, pharmacological effect, clinical use, indications, and/or other characteristics of drug products.

Utilizing FFS beneficiary: A Medi-Cal beneficiary with at least one FFS prescription filled during the measurement period

PHYSICIAN-ADMINISTERED DRUGS: 2nd QUARTER 2016

Utilization of physician-administered drugs during the second quarter of 2016 (April – June 2016) is presented below, stratified by category. In order to show changes in utilization over time, **Table 1** shows the comparison to the prior quarter (2016 Q1) and **Table 2** shows the comparison to the prior-year quarter (2015 Q2).

Table 1: 2016 Q2 Physician-Administered Drugs: Change from 2016 Q1 (one quarter)

Category	Total Utilizing Beneficiaries	% Change from 2016 Q1	Total Paid Claims	% Change from 2016 Q1	Total Reimbursement Dollars Paid	% Change from 2016 Q1
PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)	16,079	**-15.6%**	25,834	**-11.9%**	$791,702	**5.6%**
PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED	276,103	**-4.1%**	660,119	**-2.1%**	$66,223,251	**-8.6%**
MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)	114,543	**-12.0%**	236,784	**-11.3%**	$2,750,495	**-9.5%**
TOTAL	406,725	**-6.9%**	922,737	**-5.0%**	$69,765,447	**-8.5%**

Table 2: 2016 Q2 Physician-Administered Drugs: Change from 2015 Q2 (one year)

Category	Total Utilizing Beneficiaries	% Change from 2015 Q2	Total Paid Claims	% Change from 2015 Q2	Total Reimbursement Dollars Paid	% Change from 2015 Q2
PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)	16,079	**-0.8%**	25,834	**-4.9%**	$791,702	**13.7%**
PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED	276,103	**-7.4%**	660,119	**-5.8%**	$66,223,251	**-5.0%**
MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)	114,543	**-9.8%**	236,784	**-7.3%**	$2,750,495	**-11.9%**
TOTAL	406,725	**-7.9%**	922,737	**-6.2%**	$69,765,447	**-5.1%**

The following three tables show the top 20 physician-administered drugs by total utilizing beneficiaries (**Table 3**), total reimbursement dollars paid (**Table 4**), and reimbursement paid per utilizing beneficiary (**Table 5**). Each table has the comparison to the prior quarter and the prior-year quarter, for reference. In addition, the prior-year ranking is given to show changes in utilization of a drug over time.

Table 3: Top 20 Physician-Administered Drugs by *Total Utilizing Beneficiaries*								
Rank	Last Year Rank	HCPCS Code	Drug Description	2016 Q2 Total Utilizing Beneficiaries	% Change Total Utilizing Beneficiaries from 2016 Q1	% Change Total Utilizing Beneficiaries from 2015 Q2	2016 Q2 Total Reimbursement Dollars Paid	2016 Q2 Total Paid Claims
1	1	J3490	MEDROXYPROGESTERONE ACETATE	41,899	-2.7%	-8.1%	$2,763,470	42,873
2	2	J3490	LEVONORGESTREL	29,390	-1.3%	-10.8%	$894,334	30,814
3	5	S4993	LEVONORGESTREL-ETHIN ESTRADIOL	21,886	-2.7%	-10.7%	$2,643,902	22,288
4	4	J2405	ONDANSETRON HCL/PF	21,601	17.2%	7.0%	$121,574	26,243
5	3	J3490	ULIPRISTAL ACETATE	21,532	-6.3%	-16.6%	$663,298	22,597
6	6	J1885	KETOROLAC TROMETHAMINE	18,483	7.5%	12.6%	$116,476	20,473
7	7	X7700	0.9 % SODIUM CHLORIDE	14,881	61.8%	48.3%	$358,860	23,981
8	8	J2270	MORPHINE SULFATE	11,985	17.1%	-3.7%	$80,537	14,345
9	9	S4993	NORGESTIMATE-ETHINYL ESTRADIOL	10,599	-6.1%	-16.4%	$1,215,965	10,855
10	10	J0696	CEFTRIAXONE SODIUM	9,813	-5.3%	-8.0%	$61,876	10,622
11	11	Z7610	ACETAMINOPHEN	9,613	-5.5%	2.5%	$87,434	11,028
12	13	Q0144	AZITHROMYCIN	9,537	8.2%	6.4%	$83,447	9,913
13	12	J7307	ETONOGESTREL	9,412	-4.8%	-0.4%	$6,817,912	9,412
14	17	Z7610	IBUPROFEN	8,056	-12.9%	-5.1%	$67,767	8,367
15	15	Z7610	HYDROCODONE/ACETAMINOPHEN	7,230	5.5%	-11.2%	$76,775	7,945
16	18	J3010	FENTANYL CITRATE/PF	7,217	7.8%	-6.5%	$38,016	8,129
17	19	J1100	DEXAMETHASONE SOD PHOSPHATE	7,107	10.9%	19.0%	$50,629	9,500
18	14	J1170	HYDROMORPHONE HCL	6,856	24.7%	2.9%	$57,517	9,219
19	25	S0191	MISOPROSTOL	6,357	-5.4%	4.4%	$12,405	6,433
20	26	S0190	MIFEPRISTONE	6,044	-6.4%	3.7%	$426,208	6,056

Table 4: Top 20 Physician-Administered Drugs by *Total Reimbursement Dollars Paid*									
Rank	Last Year Rank	HCPCS Code	Drug Description	2016 Q2 Total Reimburse-ment Dollars Paid	% Change Total Reimburse-ment Dollars from 2016 Q1	% Change Total Reimburse-ment Dollars from 2015 Q2	2016 Q2 Total Utilizing Beneficiaries	2016 Q2 Total Paid Claims
1	1	J7307	ETONOGESTREL	$6,817,912	-4.9%	13.8%	9,412	9,412
2	2	J7189	COAGULATION FACTOR VIIA,RECOMB (NOVOSEVEN®)	$5,240,539	-4.7%	-1.8%	32	139
3	6	J3490	MEDROXYPROGESTERONE ACETATE	$2,763,470	-4.8%	-8.5%	41,899	42,873
4	4	J9355	TRASTUZUMAB	$2,659,890	4.2%	-23.0%	288	957
5	5	S4993	LEVONORGESTREL-ETHIN ESTRADIOL	$2,643,902	-5.0%	-13.3%	21,886	22,288
6	9	J7192	ANTIHEMOPH.FVIII,FULL LENGTH (INCLUDES ADVATE®, HELIXATE®, AND KOGENATE®)	$2,418,984	12.0%	0.4%	66	184
7	10	Q1081	EPOETIN ALFA (100 UNITS ESRD)	$2,277,969	3.8%	-0.2%	1,835	44,509
8	11	J9019	ASPARAGINASE (ERWINIA CHRYSAN)	$2,225,766	-28.6%	8.8%	28	244
9	7	J7300	INTRAUTERINE COPPER CONTRACEPTIVE	$2,141,222	-4.8%	-17.1%	3,299	3,309
10	12	J1745	INFLIXIMAB	$2,114,592	6.5%	14.3%	433	883
11	8	J2505	PEGFILGRASTIM	$1,878,183	-3.9%	-22.9%	267	554
12	13	J7304	NORELGESTROMIN/ETHIN. ESTRADIOL	$1,463,443	-18.3%	-14.1%	4,206	4,271
13	16	S4993	NORGESTIMATE-ETHINYL ESTRADIOL	$1,215,965	-9.0%	-17.7%	10,599	10,855
14	15	J9035	BEVACIZUMAB	$1,195,808	-16.0%	-24.1%	244	565
15	19	J1300	ECULIZUMAB	$1,185,639	-18.9%	-2.0%	20	113
16	18	J9306	PERTUZUMAB	$1,113,324	3.7%	-14.0%	108	744
17	25	J9266	PEGASPARGASE	$1,082,550	6.7%	38.7%	107	146
18	20	J0886	EPOETIN ALFA (1000 UNITS ESRD)	$985,144	-8.9%	-14.5%	800	15,275
19	3	J7302	LEVONORGESTREL	$894,334	-77.3%	-82.4%	29,390	30,814
20	14	J7303	ETONOGESTREL/ETHINYL ESTRADIOL	$879,930	-26.1%	-45.0%	5,780	5,808

Table 5: Top 20 Physician-Administered Drugs by *Reimbursement Paid per Utilizing Beneficiary*								
Rank	Last Year Rank	HCPCS Code	Drug Description	2016 Q2 Reimburse-ment Dollars Paid per Utilizing Beneficiary	% Change Reimburse-ment Dollars Paid per Utilizing Beneficiary from 2016 Q1	% Change Reimburse-ment Dollars Paid per Utilizing Beneficiary from 2015 Q2	2016 Q2 Total Reimburse-ment Dollars Paid	2016 Q2 Total Utilizing Beneficiaries
1	1	J1322	ELOSULFASE ALFA	$165,974	**10.7%**	**11.4%**	$497,922	3
2	3	J7189	COAGULATION FACTOR VIIA,RECOMB (NOVOSEVEN®)	$163,767	**22.1%**	**28.8%**	$5,240,539	32
3	2	J7181	FACTOR XIII A-SUBUNIT,RECOMB (TRETTEN®)	$136,305	**17.4%**	**3.1%**	$272,610	2
4	4	J7201	FACTOR IX REC, FC FUSION PROTN (ALPROLIX®)	$119,627	**3.5%**	**17.0%**	$478,508	4
5	24	J9307	PRALATREXATE[1]	$107,918	**N/A**	**379.6%**	$107,918	1
6	6	J1458	GALSULFASE	$107,871	**2.5%**	**41.4%**	$539,355	5
7	5	J1743	IDURSULFASE	$106,569	**16.0%**	**7.6%**	$639,411	6
8	11	J9019	ASPARAGINASE (ERWINIA CHRYSAN)	$79,492	**4.5%**	**39.9%**	$2,225,766	28
9	8	J0221	ALGLUCOSIDASE ALFA	$77,949	**15.6%**	**28.8%**	$155,898	2
10	34	J9315	ROMIDEPSIN[2]	$75,185	**145.8%**	**425.2%**	$75,185	1
11	13	J1786	IMIGLUCERASE	$72,429	**79.6%**	**91.7%**	$144,858	2
12	21	J7185	ANTIHEMOPH.FVIII,B-DOMAIN DEL (XYNTHA®)	$67,314	**-22.0%**	**187.7%**	$201,942	3
13	7	J1300	ECULIZUMAB	$59,282	**-14.9%**	**-16.7%**	$1,185,639	20
14	28	Q9975	ANTIHEMOPH.FVIII REC,FC FUSION (ELOCTATE®)	$59,118	**-15.3%**	**187.4%**	$472,946	8
15	20	J3385	VELAGLUCERASE ALFA	$45,859	**17.4%**	**86.8%**	$45,859	1
16	12	J0180	AGALSIDASE BETA	$42,024	**-38.6%**	**-22.7%**	$252,146	6
17	10	J7198	ANTI-INHIBITOR COAGULANT COMP. (FEIBA NF®)	$38,395	**-62.5%**	**-33.4%**	$191,974	5
18	23	J1931	LARONIDASE	$37,644	**-12.3%**	**65.3%**	$75,288	2
19	25	J7192	ANTIHEMOPH.FVIII,FULL LENGTH (INCLUDES ADVATE®, HELIXATE®, AND KOGENATE®)	$36,651	**10.3%**	**65.8%**	$2,418,984	66
20	22	J9027	CLOFARABINE	$29,099	**69.3%**	**27.5%**	$29,099	1

[1]In 2016 Q2, only one beneficiary had eight paid claims for this drug and in 2016 Q1 there were no beneficiaries with paid claims for this drug, and in 2015 Q2 there was one beneficiary with two paid claims for this drug.

[2]In 2016 Q2, only one beneficiary had eight paid claims for this drug and in 2016 Q1 there was one beneficiary with seven paid claims, and in 2015 Q2 there were two beneficiaries with twelve paid claims for this drug.

PROSPECTIVE DUR REVIEW

DATE OF REVIEW: October 11, 2016

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- ANALGESICS, NARCOTICS
- ANGIOTENSIN II RECEPTOR BLOCKER-BETA BLOCKER COMB.
- ANTI-ARTHRITIC, FOLATE ANTAGONIST AGENTS
- ANTIHYPERGLYCEMIC-SGLT2 INHIBITOR & BIGUANIDE COMB
- ANTIHYPERLIPIDEMIC - PCSK9 INHIBITORS
- ANTIHYPERTENSIVES, ACE INHIBITORS
- CONTRACEPTIVES,ORAL
- HEPATITIS C VIRUS - NS5A, NS3/4A, NS5B INHIB CMB.
- NON-NARC ANTITUSS-1ST ANTIHIST-DECONG-ANALG-EXPECT
- OTIC PREPARATIONS,ANTI-INFLAMMATORY-ANTIBIOTICS
- OXYTOCICS
- PLATELET AGGREGATION INHIBITORS
- TETRACYCLINES
- TOPICAL ANTI-INFLAMMATORY, NSAIDS
- VASODILATORS,CORONARY

DRUG PROBLEM TYPES: Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Underutilization (LR), Additive Toxicity (AT), Ingredient Duplication (ID), Drug-Age (PA), High Dose (HD), Low Dose (LD)

BACKGROUND: Each week new Generic Code Number (GCN) sequence numbers are added. Prospective DUR alerts for Overutilization (ER) and Severity Level 1 Drug-Drug Interactions (DD) are automatically turned on for all new GCNs.

ISSUES: New GCNs are reviewed and cross-referenced to the Medi-Cal target drug list for prospective DUR. If a GCN matches a drug on the Medi-Cal target drug list, the prospective DUR alert profile for the existing GCN is used to set the alert profile for the new GCN. A list of new GCNs with alerts turned on other than ER and DD is provided to the DUR Board for review at each DUR Board meeting.

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Review list of GCNs with prospective DUR alerts turned on between July 1, 2016 and September 30, 2016 (**Table 1**).
- Any DUR Board recommendations for additions, deletions, and/or changes will be submitted to DHCS for review. Status of recommendations will be reported to the DUR Board at DUR Board meetings, as needed.

Table 1. New GCNs for Existing DUR Target Drugs: Q3 2016 (07/01/16 – 09/30/16).

Date	GCN	Drug Description	Additional Alerts Turned on
7/13/2016	076280	FENTANYL/BUPIVACAINE/NS/PF	DA, MC, TD, AT, ID, HD, LD
	076310	DOXYCYCLINE/SKIN CLEANSER #19	PG
	076321	DOXYCYCLINE HYCLATE	PG
7/20/2016	076244	MORPHINE SULFATE IN 0.9 % NACL	DA, MC, TD, AT, ID, HD, LD
	076334	FENTANYL CITRATE/PF	DA, MC, TD, AT, ID, HD, LD
	076329	METHOTREXATE/PF	PG
	076353	EVOLOCUMAB	PG
7/27/2016	076361	OXYCODONE HCL	DA, MC, TD, AT, ID, HD, LD
	076092	CPM/PE/DM/ACETAMINOPHEN/GUAIFN	ID, HD
8/3/2016	076404	OMBITA/PARITAP/RITON/DASABUVIR	ID
8/10/2016	076088	CIPROFLOXACIN HCL/FLUOCINOLONE	MC, TD, ID, HD, LD
	076442	LISINOPRIL	PG
	076254	NEBIVOLOL HCL/VALSARTAN	PG
9/21/2016	076551	DICLOFENAC SODIUM/CAPSAICIN	DA, PG, MC, TD, ID, HD, LD
9/28/2016	076607	ASPIRIN/OMEPRAZOLE	PG, TD, ID, HD, LD
	076608		
	076262	NITROGLYCERIN	TD, ID, HD, LD
	070910	NORETHINDRONE-E.ESTRADIOL-IRON	PG, MC, TD, ID, HD, LD
	076611	OXYTOCIN/0.9 % SODIUM CHLORIDE	PG
	076620	CANAGLIFLOZIN/METFORMIN HCL	MC, TD, HD, LD
	076621		
	076622		
	076623		

PROSPECTIVE DUR REVIEW

DATE OF REVIEW: October 11, 2016

DRUG PROBLEM TYPES: Therapeutic Duplication (TD)

BACKGROUND: The Therapeutic Duplication (TD) alert is generated when a patient receives two or more drugs from the same therapeutic or pharmacologic class, such that the combined daily dose increases the risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit. The therapeutic duplication screening system warns pharmacists when a claim is submitted for select systemically absorbed target drugs that share the same therapeutic or pharmacologic class and route of administration as a drug in the patient's active paid claims medication history. Insulins, anticonvulsants, antituberculars, sublingual nitrates, aerosol nitroglycerin and aerosol dosage forms of anti-asthmatic beta agonist agents are excluded from the therapeutic duplication screen.

ISSUES: At the DUR Board meeting in February 2015, the DUR Board motioned to have the reference material for the TD alert listed in Section 25 (DUR Appendix A: Duplicate Therapy) reviewed on an annual basis, in order to update the drugs and drug categories with new drugs added to the Medi-Cal List of Contract Drugs and/or the main target drug list for prospective DUR.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: Section 25 of the DUR Manual is in need of revisions due to the addition of new target drugs and modifications to drug therapeutic categories. The proposed version of Section 25 is attached for review, with the following changes incorporated:

- The addition of the following drug therapeutic category: ANTINEOPLASTICS along with the deletion of STEROID ANTINEOPLASTICS as a separate drug therapeutic category
- The addition of the following drug therapeutic categories (under ANTIHYPERLIPIDEMICS): APO B SYNTHESIS INHIBITORS, PCSK-9 INHIBITORS, MTP INHIBITORS
- Addition of GRISEOFULVIN to ANTIFUNGALS and DIFLUNISAL to NON-STEROIDAL ANTI-INFLAMMATORY DRUGS
- Minor formatting updates to combine subcategories

PROPOSED INTERVENTION RECOMMENDATIONS TO THE DUR BOARD:

- Review and make recommendations regarding proposed changes to Section 25 of the DUR Manual.
- Continue to review Section 25 on an annual basis, with any proposed edits to be presented to the DUR Board at the first DUR Board meeting of each calendar year.

DUR Appendix A: Duplicate Therapy Section 25

ALPHA/BETA-ADRENERGIC BLOCKING AGENTS
CARVEDILOL
LABETALOL

ALPHA-ADRENERGIC BLOCKING AGENTS
DOXAZOSIN
PRAZOSIN
TERAZOSIN

ANALGESIC/ANTIPYRETICS, NON-SALICYLATE
ACETAMINOPHEN

ANALGESICS, NARCOTICS
ACETAMINOPHEN WITH CODEINE
BUPRENORPHINE
BUTORPHANOL
CODEINE
DIHYDROCODEINE
FENTANYL
HYDROCODONE
HYDROMORPHONE
LEVORPHANOL
MEPERIDINE
METHADONE
MORPHINE
NALBUPHINE
OPIUM
OXYCODONE
OXYMORPHONE
PENTAZOCINE
TAPENTADOL
TRAMADOL

ANDROGENIC AGENTS
FLUOXYMESTERONE
METHANDROSTENOLONE
METHYLTESTOSTERONE
NANDROLONE
OXANDROLONE
OXYMETHOLONE
STANOZOLOL
TESTOSTERONE

ANTIANXIETY DRUGS
ALPRAZOLAM
BUSPIRONE
CHLORDIAZEPOXIDE
DIAZEPAM
LORAZEPAM
MEPROBAMATE
OXAZEPAM

ANTIASTHMATICS
BETA-ADRENERGIC AGENTS
- ALBUTEROL
- ARFORMOTEROL
- BITOLTEROL
- FORMOTEROL
- INDACATEROL
- LEVALBUTEROL
- METAPROTERENOL
- OLODATEROL
- PIRBUTEROL
- SALMETEROL
- TERBUTALINE

MAST CELL STABILIZERS
- CROMOLYN
- NEDOCROMIL

XANTHINES
- AMINOPHYLLINE
- DYPHYLLINE
- THEOPHYLLINE

ANTIBIOTICS
ABSORBABLE SULFONAMIDES
- SULFADIAZINE
- SULFAMETHIZOLE
- SULFAMETHOXAZOLE
- SULFAMETHOXAZOLE/TRIMETHOPRIM
- SULFASALAZINE
- SULFATHIAZOLE
- SULFISOXAZOLE

ANAEROBIC ANTIPROTOZOAL-ANTIBACTERIAL AGENTS
- METRONIDAZOLE

CEPHALOSPORINS
- CEFACLOR
- CEFADROXIL
- CEFAZOLIN
- CEFDINIR
- CEFDITOREN
- CEFEPIME
- CEFIXIME
- CEFOTAXIME
- CEFOTETAN
- CEFOXITIN
- CEFPODOXIME
- CEFPROZIL
- CEFTAZIDIME
- CEFTIBUTEN
- CEFTRIAXONE
- CEFUROXIME
- CEPHALEXIN

ANTIBIOTICS (continued)
LINCOSAMIDES
- CLINDAMYCIN
- LINCOMYCIN

MACROLIDES
- AZITHROMYCIN
- CLARITHROMYCIN
- ERYTHROMYCIN
- FIDAXOMICIN

NITROFURAN DERIVATIVES
- NITROFURANTOIN

PENICILLINS
- AMOXICILLIN
- AMPICILLIN
- CLOXACILLIN
- DICLOXACILLIN
- NAFCILLIN
- OXACILLIN
- PENICILLIN
- PIPERACILLIN
- TICARCILLIN

QUINOLONES
- CIPROFLOXACIN
- GATIFLOXACIN
- GEMIFLOXACIN
- LEVOFLOXACIN
- MOXIFLOXACIN
- NORFLOXACIN
- OFLOXACIN

TETRACYCLINES
- DEMECLOCYCLINE
- DOXYCYCLINE
- MINOCYCLINE
- TETRACYCLINE

ANTICONVULSANTS
CARBAMAZEPINE
CHLORDIAZEPOXIDE
CLOBAZAM
CLONAZEPAM
DIAZEPAM
DIVALPROEX
ESLICARBAZEPINE
ETHOSUXIMIDE
ETHOTOIN
EZOGABINE
FELBAMATE
FOSPHENYTOIN
GABAPENTIN
LACOSAMIDE
LAMOTRIGINE
LEVETIRACETAM
METHSUXIMIDE
MEPHOBARBITAL
OXCARBAZEPINE

ANTICONVULSANTS (continued)
PERAMPANEL
PHENACEMIDE
PHENSUXIMIDE
PHENYTOIN
PREGABALIN
PRIMIDONE
RUFINAMIDE
TIAGABINE
TOPIRAMATE
TRIMETHADIONE
VALPROIC ACID
VIGABATRIN
ZONISAMIDE

ANTIDEPRESSANTS
NOREPINEPHRINE AND DOPAMINE REUPTAKE INHIBITORS (NDRIS)
- BUPROPION

SELECTIVE SEROTONIN REUPTAKE INHIBITORS (SSRIS)
- CITALOPRAM
- ESCITALOPRAM
- FLUOXETINE
- FLUVOXAMINE
- PAROXETINE
- SERTRALINE
- ST. JOHN'S WORT

SEROTONIN-2 ANTAGONIST/REUPTAKE INHIBITORS (SARIS)
- NEFAZODONE
- TRAZODONE

SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRIS)
- DESVENLAFAXINE
- DULOXETINE
- LEVOMILNACIPRAN
- VENLAFAXINE

SSRI & SEROTONIN RECEPTOR MODULATOR ANTIDEPRESSANT
- VORTIOXETINE

TRICYCLIC ANTIDEPRESSANTS & RELATED NON-SELECTIVE REUPTAKE INHIBITORS
- AMITRIPTYLINE
- AMOXAPINE
- CLOMIPRAMINE
- DESIPRAMINE
- DOXEPIN
- IMIPRAMINE
- MAPROTILINE
- NORTRIPTYLINE
- PROTRIPTYLINE
- TRIMIPRAMINE

ANTIDIARRHEALS
BISMUTH
DIPHENOXYLATE/ATROPINE
LOPERAMIDE
OPIUM TINCTURE
PAREGORIC

ANTIFUNGALS
CLOTRIMAZOLE
FLUCONAZOLE
FLUCYTOSINE
GRISEOFULVIN
ITRACONAZOLE
KETOCONAZOLE
MICONAZOLE
POSACONAZOLE
TERBINAFINE
VORICONAZOLE

ANTIHYPERGLYCEMICS
ALPHA-GLUCOSIDASE INHIBITORS
- ACARBOSE
- MIGLITOL

AMYLIN ANALOG-TYPE
- PRAMLINTIDE

BIGUANIDE TYPE
- METFORMIN

DPP-4 INHIBITORS
- ALOGLIPTIN
- LINAGLIPTIN
- SAXAGLIPTIN
- SITAGLIPTIN

INCRETIN MIMETIC (GLP-1 RECEPTOR AGONIST)
- ALBIGLUTIDE
- DULAGLUTIDE
- EXENATIDE
- EXENATIDE MICROSPHERES
- LIRAGLUTIDE

INSULIN-RELEASE STIMULANT TYPE
- CHLORPROPAMIDE
- GLIMEPIRIDE
- GLIPIZIDE
- GLYBURIDE
- GLYBURIDE, MICRONIZED
- NATEGLINIDE
- REPAGLINIDE
- TOLAZAMIDE
- TOLBUTAMIDE

SOD/GLUC COTRANSPORT2 (SGLT2) INHIBITORS
- CANAGLIFLOZIN
- DAPAGLIFLOZIN PROPANEDIOL
- EMPAGLIFLOZIN

ANTIHYPERGLYCEMICS (continued)
THIAZOLIDINEDIONE (PPARG AGONIST)
- PIOGLITAZONE
- ROSIGLITAZONE

ANTIHYPERLIPIDEMICS
HMG COA REDUCTASE INHIBITORS
ATORVASTATIN
FLUVASTATIN
LOVASTATIN
PITAVASTATIN
PRAVASTATIN
ROSUVASTATIN
SIMVASTATIN
APO B SYNTHESIS INHIBITOR
MIPOMERSEN
PCSK-9 INHIBITORS
ALIROCUMAB
EVOLOCUMAB
MTP INHIBITOR
LOMITAPIDE

ANTIHYPERTENSIVES
ACE INHIBITORS
BENAZEPRIL
CAPTOPRIL
ENALAPRIL
FOSINOPRIL
LISINOPRIL
MOEXIPRIL
PERINDOPRIL
QUINAPRIL
RAMIPRIL
TRANDOLAPRIL
ANGIOTENSIN RECEPTOR ANTAGONIST
AZILSARTAN MEDOXOMIL
CANDESARTAN CILEXETIL
EPROSARTAN
IRBESARTAN
LOSARTAN
OLMESARTAN MEDOXOMIL
TELMISARTAN
VALSARTAN
SYMPATHOLYTIC
CLONIDINE
GUANFACINE
METHYLDOPA
METHYLDOPATE
RESERPINE

ANTI-INFLAMMATORY TUMOR NECROSIS FACTOR INHIBITOR

ADALIMUMAB
ETANERCEPT
GOLIMUMAB

ANTINEOPLASTICS

ABIRATERONE
ADO-TRASTUZUMAB EMTANSINE
AFATINIB
ALDESLEUKIN
ALECTINIB
ALITRETINOIN
ALTRETAMINE
ANASTROZOLE
ARSENIC TRIOXIDE
ATEZOLIZUMAB
AXITINIB
AZACITIDINE
BELINOSTAT
BENDAMUSTINE
BEVACIZUMAB
BEXAROTENE
BICALUTAMIDE
BLEOMYCIN
BORTEZOMIB
BOSUTINIB
BRENTUXIMAB
BUSULFAN
CABAZITAXEL
CABOZANTINIB
CAPECITABINE
CARBOPLATIN
CARMUSTINE
CERITINIB
CETUXIMAB
CHLORAMBUCIL
CHLOROTRIANISENE
CISPLATIN
CLADRIBINE
CLOFARABINE
COBIMETINIB
CRIZOTINIB
CYCLOPHOSPHAMIDE
CYTARABINE
DABRAFENIB
DACARBAZINE
DARATUMUMAB
DASATINIB
DAUNORUBICIN
DECITABINE
DEGARELIX
DENILEUKIN
DIENESTROL
DOCETAXEL

ANTINEOPLASTICS (continued)

DOXORUBICIN
ELOTUZUMAB
ENZALUTAMIDE
EPIRUBICIN
ERIBULIN
ERLOTINIB
ESTRADIOL
ESTRAMUSTINE
ETHINYL ESTRADIOL
ETOPOSIDE
ETOPOSIDE
EVEROLIMUS
EXEMESTANE
FLOXURIDINE
FLUDARABINE
FLUOROURACIL
FLUOXYMESTERONE
FLUTAMIDE
FULVESTRANT
GEFITINIB
GEMCITABINE
GEMTUZUMAB
GOSERELIN
HYDROXYUREA
IDARUBICIN
IDELALISIB
IFOSFAMIDE
IMATINIB
INTERFERON
IPILIMUMAB
IRINOTECAN
IXABEPILONE
IXAZOMIB
LENALIDOMIDE
LAPATINIB
LENVATINIB
LETROZOLE
LEUPROLIDE
LOMUSTINE
MECHLORETHAMINE
MEDROXYPROGESTERONE
MEGESTROL
MELPHALAN
MERCAPTOPURINE
METHOTREXATE
METHYL TESTOSTERONE
MITOMYCIN
MITOTANE
MITOXANTRONE
NECITUMUMAB
NELARABINE
NILOTINIB
NILUTAMIDE
NIVOLUMAB
OBINUTUZUMAB

ANTINEOPLASTICS (continued)
OFATUMUMAB
OLAPARIB
OMACETAXINE
OSIMERTINIB
OXALIPLATIN
PACLITAXEL
PALBOCICLIB
PANOBINOSTAT
PAZOPANIB
PEGASPARGASE
PEGINTERFERON
PEMBROLIZUMAB
PEMETREXED
PENTOSTATIN
PERTUZUMAB
PIPOBROMAN
PLICAMYCIN
POLYESTRADIOL
POMALIDOMIDE
PONATINIB
PORFIMER
PROCARBAZINE
RAMUCIRUMAB
REGORAFENIB
RITUXIMAB
ROMIDEPSIN
SONIDEGIB
SORAFENIB
STREPTOZOCIN
SUNITINIB
TAMOXIFEN
TEMOZOLOMIDE
TENIPOSIDE
TESTOLACTONE
TESTOSTERONE
THIOGUANINE
THIOTEPA
TOPOTECAN
TRABECTEDIN
TRAMETINIB
TRASTUZUMAB
TRETINOIN
TRIPTORELIN
URACIL
VALRUBICIN
VANDETANIB
VEMURAFENIB
VENETOCLAX
VINBLASTINE
VINCRISTINE
VINORELBINE
VISMODEGIB
VORINOSTAT
ZIV-AFLIBERCEPT

ANTIPARKINSONISM DRUGS, ANTICHOLINERGIC
BENZTROPINE
TRIHEXYPHENIDYL

ANTIPSYCHOTICS
ATYPICAL, D2 PARTIAL AGONIST/5HT MIXED
- ARIPIPRAZOLE

ATYPICAL, DOPAMINE & SEROTONIN ANTAGONISTS
- ASENAPINE
- CLOZAPINE
- ILOPERIDONE
- LURASIDONE
- OLANZAPINE
- PALIPERIDONE
- QUETIAPINE
- RISPERIDONE
- ZIPRASIDONE

DOPAMINE & SEROTONIN ANTAGONISTS
- LOXAPINE

DOPAMINE ANTAGONISTS, BUTYROPHENONES
- DROPERIDOL
- HALOPERIDOL

DOPAMINE ANTAGONISTS, DIPHENYLBUTYLPIPERIDINES
- PIMOZIDE

DOPAMINE ANTAGONISTS, THIOXANTHENES
- THIOTHIXENE

DOPAMINE ANTAGONISTS, DIHYDROINDOLONES
- MOLINDONE

PHENOTHIAZINES
- CHLORPROMAZINE
- FLUPHENAZINE
- PERPHENAZINE
- THIORIDAZINE
- TRIFLUOPERAZINE

ANTIRETROVIRALS, HIV-SPECIFIC
CCR5 CO-RECEPTOR ANTAGONISTS
- MARAVIROC

FUSION INHIBITORS
- ENFUVIRTIDE

HIV-1 INTEGRASE STRAND TRANSFER INHIBITORS
- DOLUTEGRAVIR
- RALTEGRAVIR

NON-NUCLEOSIDE, RTI
- DELAVIRDINE
- EFAVIRENZ
- ETRAVIRINE
- NEVIRAPINE
- RILPIVIRINE

NON-PEPTIDIC PROTEASE INHIBITORS
- DARUNAVIR
- TIPRANAVIR

ANTIRETROVIRALS, HIV-SPECIFIC (continued)
NUCLEOTIDE ANALOG, RTI
- ABACAVIR
- DIDANOSINE
- EMTRICITABINE
- LAMIVUDINE
- STAVUDINE
- TENOFOVIR
- ZIDOVUDINE

PROTEASE INHIBITORS
- ATAZANAVIR
- FOSAMPRENAVIR
- INDINAVIR
- NELFINAVIR
- RITONAVIR
- SAQUINAVIR

ANTI-ULCER PREPARATIONS
MISOPROSTOL
SUCRALFATE

ANTIVIRALS, GENERAL
ACYCLOVIR
CIDOFOVIR
FAMICICLOVIR
FOSCARNET
GANCICLOVIR
OSELTAMIVIR
RIMANTADINE
VALACYCLOVIR
VALGANCICLOVIR
ZANAMIVIR

BARBITURATES
AMOBARBITAL
BUTABARBITAL
PENTOBARBITAL
PHENOBARBITAL
SECOBARBITAL

BETA-ADRENERGIC BLOCKING AGENTS
ACEBUTOLOL
ATENOLOL
BETAXOLOL
BISOPROLOL
CARTEOLOL
ESMOLOL
METOPROLOL
NADOLOL
NEBIVOLOL
PENBUTOLOL
PINDOLOL
PROPRANOLOL
SOTALOL
TIMOLOL

BIPOLOAR DISORDER DRUGS
CARBAMAZEPINE
LITHIUM

BONE RESORPTION INHIBITORS
ALENDRONATE
CALCITONIN
DENOSUMAB
ETIDRONATE
IBANDRONATE
PAMIDRONATE
RALOXIFENE
RISEDRONATE
TILUDRONATE
ZOLEDRONIC ACID

CALCIUM CHANNEL BLOCKING AGENTS
AMLODIPINE
BEPRIDIL
CLEVIDIPINE
DILTIAZEM
FELODIPINE
ISRADIPINE
NICARDIPINE
NIFEDIPINE
NIMODIPINE
NISOLDIPINE
VERAPAMIL

CONTRACEPTIVES
INTRAVAGINAL, SYSTEMIC
- ETONOGESTREL/ETHINYL ESTRADIOL

ORAL
- DESOGESTREL – ETHINYL ESTRADIOL
- DROSPIR/ETH ESTRA/LEVOMEFOL CA
- ESTRADIOL VALERATE/DIENOGEST
- ETHINYL ESTRADIOL/DROSPIRENONE
- ETHYNODIOL D – ETHINYL ESTRADIOL
- ETHYNODIOL DIACETATE – MESTRANOL
- LEVONORGESTREL
- LEVONORGESTREL – ETHINYL ESTRADIOL
- NORETHINDRONE
- NORETHINDRONE – ETHINYL ESTRADIOL
- NORETHINDRONE – MESTRANOL
- NORGESTIMATE – ETHINYL ESTRADIOL
- NORGESTREL
- NORGESTREL – ETHINYL ESTRADIOL
- ULIPRISTAL ACETATE

TRANSDERMAL
- NORELGESTROMIN/ETHINYL ESTRADIOL

DIGITALIS GLYCOSIDES
DIGITOXIN
DIGOXIN

DIURETICS
LOOP
- BUMETANIDE
- ETHACRYNATE
- ETHACRYNIC ACID
- FUROSEMIDE
- TORSEMIDE

POTASSIUM SPARING
- AMILORIDE
- EPLERENONE
- SPIRONOLACTONE
- TRIAMTERENE

THIAZIDE AND RELATED
- BENDROFLUMETHAZIDE
- CHLOROTHIAZIDE
- CHLORTHALIDONE
- HYDROCHLOROTHIAZIDE
- INDAPAMIDE
- METHYCLOTHIAZIDE
- METOLAZONE

ERYTHROPOIESIS-STIMULATING AGENTS
DARBEPOETIN ALFA
EPOETIN ALFA

ESTROGENIC AGENTS
DIETHYLSTILBESTROL
ESTRADIOL
ESTROGENS, CONJUGATED
ESTROGENS, ESTERIFIED
ESTRONE
ESTROPIPATE
ETHINYL ESTRADIOL
POLYESTRADIOL

GROWTH HORMONES
INTERFERON GAMMA-1B, RECOMBINANT
SOMATREM
SOMATROPIN

HISTAMINE H2-RECEPTOR INHIBITORS
CIMETIDINE
FAMOTIDINE
NIZATIDINE
RANITIDINE

INTESTINAL MOTILITY STIMULANTS
METOCLOPRAMIDE

NON-STEROIDAL ANTI-INFLAMMATORY DRUGS
BROMFENAC
CELECOXIB
DICLOFENAC
DIFLUNISAL
ETODOLAC
FENOPROFEN
FLURBIPROFEN
IBUPROFEN
INDOMETHACIN
KETOPROFEN
KETOROLAC TROMETHAMINE
MECLOFENAMATE
MEFENAMIC ACID
MELOXICAM
NABUMETONE
NAPROXEN
OXAPROZIN
OXYPHENBUTAZONE
PIROXICAM
PHENYLBUTAZONE
SULINDAC
TOLMETIN

OTHER PSYCHOTROPICS
ADRENERGICS, AROMATIC, NON-CATECHOLAMINE
- DEXTROAMPHETAMINE/AMPHETAMINE
- LISDEXAMFETAMINE

TX FOR ATTENTION DEFICIT HYPERACTIVITY DISORDER– SELECTIVE ALPHA-2 RECEPTOR AGONIST
- CLONIDINE
- GUANFACINE

TX FOR ATTENTION DEFICIT HYPERACTIVITY (ADHD)/NARCOLEPSY
- ARMODAFINIL
- DEXMETHYLPHENIDATE
- METHYLPHENIDATE
- MODAFINIL

PLATELET AGGREGATION INHIBITORS
ABCIXIMAB
ASPIRIN/DIPYRIDAMOLE
CILOSTAZOL
CLOPIDOGREL
DIPYRIDAMOLE
EPTIFIBATIDE
PRASUGREL
TICAGRELOR
TICLOPIDINE
TIROFIBAN
VORAPAXAR

PROGESTATIONAL AGENTS
HYDROXYPROGESTERONE
MEDROXYPROGESTERONE
NORETHINDRONE
PROGESTERONE

PROTON-PUMP INHIBITORS
DEXLANSOPRAZOLE
ESOMEPRAZOLE
LANSOPRAZOLE
OMEPRAZOLE
PANTOPRAZOLE
RABEPRAZOLE

SEDATIVE-HYPNOTICS, NON-BARBITURATE
CHLORAL HYDRATE
DEXMEDETOMIDINE
DIPHENHYDRAMINE
DOXEPIN
DOXYLAMINE SUCCINATE
ESTAZOLAM
ESZOPICLONE
FLURAZEPAM
LORAZEPAM
MIDAZOLAM
PYRILAMINE
QUAZEPAM
SUVOREXANT
TEMAZEPAM
TRIAZOLAM
TRYPTOPHAN
ZALEPLON
ZOLPIDEM

THYROID HORMONES
LEVOTHYROXINE
LIOTHYRONINE
LIOTRIX
THYROID

DUR EDUCATIONAL OUTREACH TO PROVIDERS
UPDATE: METABOLIC TESTING IN CHILDREN AND ADOLESCENTS LETTER - 2016

DATE OF MAILING: TBD
DATE OF UPDATE: October 26, 2016

BACKGROUND

Effective October 1, 2014, any use of antipsychotics for Medi-Cal beneficiaries 0 – 17 years of age requires an approved *Treatment Authorization Request* (TAR). A report on the impact of this policy was presented to the DUR Board at the September 20, 2016 DUR Board meeting. At that meeting, the DUR Board recommended DUR educational outreach to providers regarding metabolic monitoring for children and adolescents using antipsychotic medications, using methods similar to the mailing conducted in August 2015.

OBJECTIVES

- To improve metabolic monitoring rates among children and adolescents in the Medi-Cal fee-for-service population with ≥ 4 paid claims for an antipsychotic medication between January 1, 2015 and September 30, 2016

METHODS

The study population identified when writing the policy impart report was used to identify Medi-Cal fee-for-service (FFS) beneficiaries in need of metabolic testing. This initial study population was comprised of a total of 2,272 children and adolescents who met the following criteria:

- Between 1 and 17 years of age (between January 1, 2015 and December 31, 2015)
- Had at least two paid claims for an antipsychotic medication between January 1, 2015 and December 31, 2015
- Did not have a paid claim for either an HbA1C/glucose or LDL-C/cholesterol test between January 1, 2015 and December 31, 2015

For the mailing, eligibility criteria was re-reviewed for each of these beneficiaries to ensure they remained continuously enrolled in the Medi-Cal fee-for-service program between January 1, 2016 (the day after the original data pull for the DUR educational bulletin) and September 30, 2016.

Further inclusion/exclusion criteria for beneficiaries to be included in the study population:

- Beneficiaries < 18 years of age through November 30, 2016

- Beneficiaries with ≥ 2 paid claims for an antipsychotic medication between January 1, 2016 and September 30, 2016 (≥ 4 paid claims total between January 1, 2015 and September 30, 2016)
- Beneficiaries currently taking an antipsychotic medication (a paid claim with a days supply extending past July 31, 2016)
- Did not have a paid claim for either an HbA1C/glucose or LDL-C/cholesterol test between January 1, 2015 and September 30, 2016
- Patient/prescriber combinations were excluded if they were already mailed letters in 2015 and a patient survey was received by the DUR program

A total of 596 beneficiaries from the original cohort of 2,272 met the above inclusion/ exclusion criteria. There were two cases where a beneficiary had two prescribers prescribing different medications concurrently so both prescribers were included in the mailing. Twenty-five patient/prescriber combinations were included in the 2015 mailing and had surveys received, although only 24 were excluded for this mailing, as one survey stated that that prescriber had no knowledge of the patient. Eleven additional prescriptions were filled from that prescriber since the 2015 mailing, so this patient/prescriber combination was included again. A total of 376 prescribers were identified for educational outreach letters.

Prescribers were mailed a letter with a summary of clinical recommendations. The mailing included the following:

- List of patients (name and date of birth) from the study population linked to this prescriber
- Medi-Cal DUR article on appropriate antipsychotic medication use among children and adolescents
- Provider response survey(s); one survey per patient

Timeframe of mailing following approval of packet by DHCS:

- Prescriber Letters (n=376)
    - October 25, 2016: packet submitted to Publications
    - TBD: final, edited packet approved by DHCS/Xerox
    - TBD: packet sent to printer
    - TBD: packet mailed to providers

OUTCOMES

- Direct costs associated with mailing: TBD
- Rate of undeliverable letters and provider response rate (within 90 days): TBD

As stated in the original proposal, the following outcome variables will need to be assessed at later time points, as medical claims data become available:

- The primary outcome variable will be whether or not the beneficiary has a laboratory test for HbA1C/glucose and/or LDL-C/cholesterol within 90 days of the mailing of the intervention letter.

- The secondary outcome variable will be the percentage of patients with additional paid claims for antipsychotic medications within 6 months following the mailing of the intervention letter (stratified by laboratory monitoring status).

In addition, prescriber response rates will be calculated, and response data and comments will be presented in aggregate in a report to DHCS and the DUR Board.

DUR EDUCATIONAL OUTREACH TO PROVIDERS
UPDATE: BUPRENORPHINE LETTER

DATE OF MAILING: TBD
DATE OF UPDATE: OCTOBER 26, 2016

BACKGROUND

Buprenorphine, both by itself and in combination with naloxone, has emerged as a first-line treatment for opioid addiction. Several reviews have concluded there is high-quality evidence to show that medication-assisted treatment with buprenorphine is effective in the maintenance treatment of opioid addiction and increases retention in treatment. Despite this success, buprenorphine treatment is highly underutilized and access is often restricted. Recent efforts at the national level have expanded access and removed restrictions to buprenorphine, including increasing the number of patients that providers are able to treat under the DATA 2000 waiver. As of August 8, 2016, qualified prescribers may now treat up to 275 patients.

A recent analysis by the Medi-Cal Drug Use Review (DUR) program found that 47% of Medi-Cal fee-for-service beneficiaries with a paid claim for buprenorphine in the past year continue to be adherent to their treatment regimen. Concomitant use of any opioid among beneficiaries with at least one paid claim for buprenorphine was also very low (3%), and even lower among the adherent group (2%).

OBJECTIVES

- To inform providers that buprenorphine use among Medi-Cal fee-for-service beneficiaries is associated with high adherence rates and decreased concomitant use of high-risk medications, including other opioids
- To increase the number of Medi-Cal patients receiving treatment with buprenorphine
- To increase the number of Medi-Cal providers able to provide buprenorphine treatment

METHODS

The top prescribers (by total quantity prescribed) of opioids in the Medi-Cal fee-for-service program between October 1, 2015 and September 30, 2016 will be cross-referenced to the list of California providers with a current waiver to provide buprenorphine treatment. A total of 100 providers who are among the top prescribers of opioids and who do not currently have a buprenorphine waiver will be sent a letter with more information about buprenorphine training.

The mailing will also include the following:

- Medi-Cal DUR article on buprenorphine
- Provider response survey for each provider

In addition, the top 100 prescribers (by total number of patients) of buprenorphine in the Medi-Cal program between October 1, 2015 and September 30, 2016 will be sent a letter thanking them for obtaining the waiver and letting them know that the maximum number of patients that qualified providers can treat has been raised to 275. The mailing will also include the following:

- Medi-Cal DUR article on buprenorphine
- Provider response survey for each provider

Timeframe of mailing following approval of packet by DHCS:

- Top Opioid Prescriber Letters (n=100)
    - October 25, 2016: packet submitted to Publications
    - TBD: final, edited packet approved by DHCS/Xerox
    - TBD: packet sent to printer
    - TBD: packet mailed to providers

- Top Buprenorphine Prescriber Letters (n=100)
    - October 25, 2016: packet submitted to Publications
    - TBD: final, edited packet approved by DHCS/Xerox
    - TBD: packet sent to printer
    - TBD: packet mailed to providers

OUTCOMES

- Direct costs associated with mailing: TBD
- Rate of undeliverable letters and provider response rate (within 90 days): TBD

As stated in the original proposal, the following outcome variables will need to be assessed at later time points, as medical claims data become available:

- The primary outcome variable will be the percentage increase in the number of patients (all of Medi-Cal) with paid claims for buprenorphine among all providers who received the mailing, calculated one year prior to and one year after the mailing of the letter.
- The following secondary outcome variables will also be assessed after one year:
    - The number of providers contacted who complete the training and applied for a waiver
    - Percentage change (by total quantity prescribed) of total opioid prescribing in the Medi-Cal fee-for-service population, by individual provider among providers contacted.

In addition, prescriber response rates will be calculated, and response data and comments will be presented in aggregate in a report to DHCS and the DUR Board.

RETROSPECTIVE DUR REVIEW

DATES OF REVIEW: October 11, 2016

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- HEP C VIRUS,NUCLEOTIDE ANALOG NS5B POLYMERASE INH
- HEP C VIRUS-NS5B POLYMERASE AND NS5A INHIB. COMBO.
- HEPATITIS C TREATMENT AGENTS
- HEPATITIS C VIRUS - NS5A REPLICATION COMPLEX INHIB
- HEPATITIS C VIRUS - NS5A, NS3/4A, NS5B INHIB CMB.
- HEPATITIS C VIRUS NS3/4A SERINE PROTEASE INHIB.
- HEPATITIS C VIRUS- NS5A AND NS3/4A INHIBITOR COMB

DRUG PROBLEM TYPES: Over Utilization (OU), Therapeutic Appropriateness (O^1)

BACKGROUND: An estimated 2.7-3.9 million people in the United States have chronic hepatitis C virus (HCV) infection, a liver disease that results from infection with the hepatitis C virus.[1] The route of transmission is primarily through contact with blood of an infected person from sharing contaminated needles, syringes, or other injection drug equipment. Less commonly, transmission can occur through sexual contact with an infected person, at birth from an infected mother, and via a needlestick or other sharp instrument injuries.[2,3] According to epidemiological studies, new cases of HCV infection within the last 15 years are predominately among young persons who are white, live in non-urban areas (particularly in Eastern and Midwestern states), have a history of injection-drug use, and have a history of opioid use.[4]

While 15%–25% of newly infected persons clear the virus, approximately 75%–85% of newly infected persons develop chronic infection.[2,3] Without treatment, HCV can last a lifetime and lead to serious liver problems, including cirrhosis (scarring of the liver) liver failure, and even liver cancer. [2,3] About half of all infected people are unaware they are infected.[5] In 2007 the number of HCV-related deaths in the United States exceeded the number of HIV/AIDS-related deaths, and has since continued to increase.[6]

Treatment options for hepatitis C virus (HCV) infection have been evolving continuously since the first introduction of highly effective HCV protease inhibitor therapies in 2011. Within the Medi-Cal fee-for-service population, these drugs are covered with an approved *Treatment Authorization Request* (TAR). In July 2015, the Department of Health Care Services revised its treatment policy for the management of chronic hepatitis C, expanding eligibility to beneficiaries with hepatitis C and light liver scarring.

ISSUES: There has been continued discussion and debate regarding the high cost of treating chronic hepatitis C with the newer protease inhibitors. On average, a 12-week course of treatment may range from $54,000 (elbasvir/grazoprevir) to $94,500 (ledipasvir/sofosbuvir).

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: Paid claims for all HCV medications with dates of service between September 1, 2015 and August 31, 2016 were reviewed for Medi-Cal fee-for-service beneficiaries. During this measurement year, a total of 571 beneficiaries were identified as having a paid claim for an HCV medication, for a total number of 1,824 paid claims. Within this cohort there were a total of 489 beneficiaries who were continuously-eligible in the Medi-Cal fee-for-service program throughout the measurement year. A review of utilization among these beneficiaries is shown below in **Table 1**.

Table 1. Utilization of HCV medications among continuously-eligible Medi-Cal fee-for-service beneficiaries ≥18 years of age with chronic hepatitis C infection (dates of service between September 1, 2015 and August 31, 2016).

Drug	Total Utilizing Beneficiaries (n=489)*	Total Paid Claims
sofosbuvir	115	391
ledipasvir/sofosbuvir	317	784
elbasvir/grazoprevir	11	26
ombitasvir/paritaprevir/ritonavir/dasabuvir	< 10	20
sofosbuvir/velpatasvir	< 10	11
simeprevir	< 10	19
ribavirin	121	317
peginterferon alfa-2b	< 10	10
peginterferon alfa-2a	< 10	23
daclatasvir	64	222

*Some beneficiaries may be on more than one medication.

Except for ribavirin, all drugs listed may only be obtained with an approved TAR. Providers must provide documentation of baseline HCV-RNA level and HCV genotype. In addition, when applicable, providers must document relevant clinical information (for example, failure of prior treatment, presence of cirrhosis, etc.) in support of medical necessity for duration of therapy. Failure to submit supporting documentation may delay authorization of the TAR.

Without specific clinical information available, including level of cirrhosis, HCV genotype, and reason for discontinuation of treatment before recommended treatment duration, it is difficult to determine whether all beneficiaries are being treated in accordance with AASLD-IDSA recommendations for first-line therapy. However, a review of medical claims data found that all 489 beneficiaries had at least one HCV-RNA level, HCV genotype test, and comprehensive metabolic panel, which follows AASLD-IDSA recommended guidelines. Further, all beneficiaries did not exceed treatment duration limits for their regimen. Finally, among this cohort there was no evidence of HCV retreatment, although the period of time reviewed was only one year and the incubation period for HCV ranges from 14 to 180 days, with an average incubation time of 45 days.[2,3]

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Given that pharmacy and medical claims data show use of these drugs follows updated clinical guidelines, further action should be limited to annual review of HCV medication use, especially to review any potential HCV retreatment in the Medi-Cal fee-for-service population.
- Periodic monitoring of utilization of high-cost drug therapeutic categories is recommended, as requested by the DUR Board.

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RETROSPECTIVE DUR REVIEW

DATE OF REVIEW: October 11, 2016

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- ANALGESICS, NARCOTICS: **buprenorphine**
- ANTIHYPERGLYCEMC-SOD/GLUC COTRANSPORT2(SGLT2)INHIB: **dapagliflozin propanediol, empagliflozin**
- ANTIHYPERGLYCEMIC, AMYLIN ANALOG-TYPE: **pramlintide acetate**
- ANTIHYPERGLYCEMIC-SGLT2 INHIBITOR & BIGUANIDE COMB: **dapagliflozin/metformin hcl**
- ANTINEOPLAST,HISTONE DEACETYLASE (HDAC) INHIBITORS: **panobinostat lactate**
- ANTINEOPLASTIC - EPOTHILONES AND ANALOGS: **ixabepilone**
- ANTINEOPLASTIC - VEGFR ANTAGONIST: **ramucirumab**
- ANTINEOPLASTIC EGF RECEPTOR BLOCKER MCLON ANTIBODY: **cetuximab**
- ANTINEOPLASTIC SYSTEMIC ENZYME INHIBITORS: **lenvatinib mesylate, olaparib, palbociclib**
- ANTINEOPLASTIC,ANTI-PROGRAMMED DEATH-1 (PD-1) MAB: **nivolumab**
- ANTIVIRALS, HIV-SPEC, NON-PEPTIDIC PROTEASE INHIB: **darunavir/cobicistat**
- ANTIVIRALS, HIV-SPECIFIC, PROTEASE INHIBITORS: **atazanavir sulfate/cobicistat**
- ANTIVIRALS,HIV-1 INTEGRASE STRAND TRANSFER INHIBTR: **elvitegravir**
- CONTRACEPTIVES, INTRAVAGINAL, SYSTEMIC: **etonogestrel/ethinyl estradiol**
- CYTOCHROME P450 INHIBITORS: **cobicistat**
- CYTOTOXIC T-LYMPHOCYTE ANTIGEN(CTLA-4)RMC ANTIBODY: **ipilimumab**
- HEP C VIRUS,NUCLEOTIDE ANALOG NS5B POLYMERASE INH: **sofosbuvir**
- HEP C VIRUS-NS5B POLYMERASE AND NS5A INHIB. COMBO.: **ledipasvir/sofosbuvir**
- HEPATITIS C VIRUS - NS5A, NS3/4A, NS5B INHIB CMB.: **ombita/paritap/riton/dasabuvir**

DRUG PROBLEM TYPES: Therapeutic Appropriateness (O^1), Overutilization (OU), Under Utilization (UU)

BACKGROUND: Each month there are usually modifications made to the Medi-Cal List of Contract Drugs, including the addition of new drugs.

ISSUES: As new drugs are added to the Medi-Cal Contract Drug List, periodic reviews of utilization patterns for these drugs should be conducted to evaluate potential drug problems.

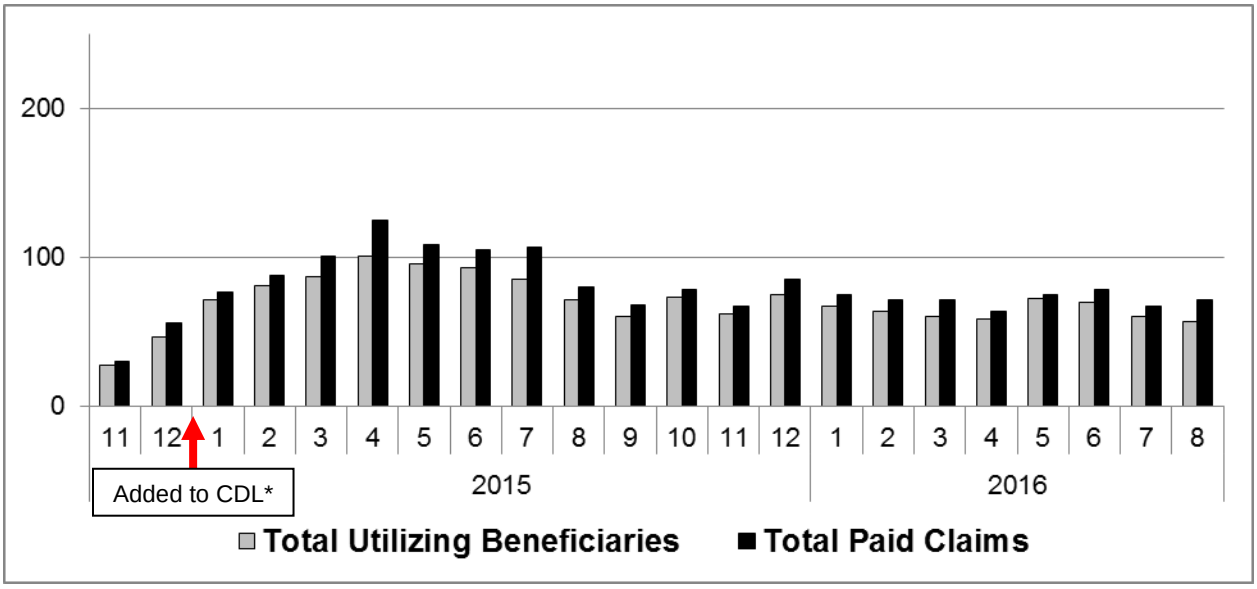
REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: During the Federal Fiscal Year 2015 (between 10/1/14 and 9/30/15), there were a total of 22 new prescription medications added to the Medi-Cal List of Contract Drugs. Utilization data (total number of paid claims and utilizing beneficiaries with at least one paid claim) were reviewed for each of these drugs during the period between 10/1/13 and 08/31/16 to allow at least 11 months of utilization data before and after the drug was added to the Medi-Cal List of Contract Drugs.

The following 12 drugs do not have graphical representations of the data presented due to low utilization (< 10 utilizing beneficiaries during all of the months reviewed):

- **cetuximab** (added July 1, 2015)
- **cobicistat** (added October 24, 2014)
- **elvitegravir** (added January 28, 2015)
- **ipilimumab** (added July 1, 2015)
- **ixabepilone** (added July 1, 2015)
- **lenvatinib** (added February 23, 2015)
- **nivolumab** (added December 26, 2014)
- **olaparib** (added December 26, 2014)
- **ombitasvir/paritaprevir/ritonavir and dasabuvir** (added July 1, 2015)
- **panobinostat** (added March 16, 2015)
- **pramlintide acetate** (added May 1, 2015)
- **ramucirumab** (added October 1, 2014)

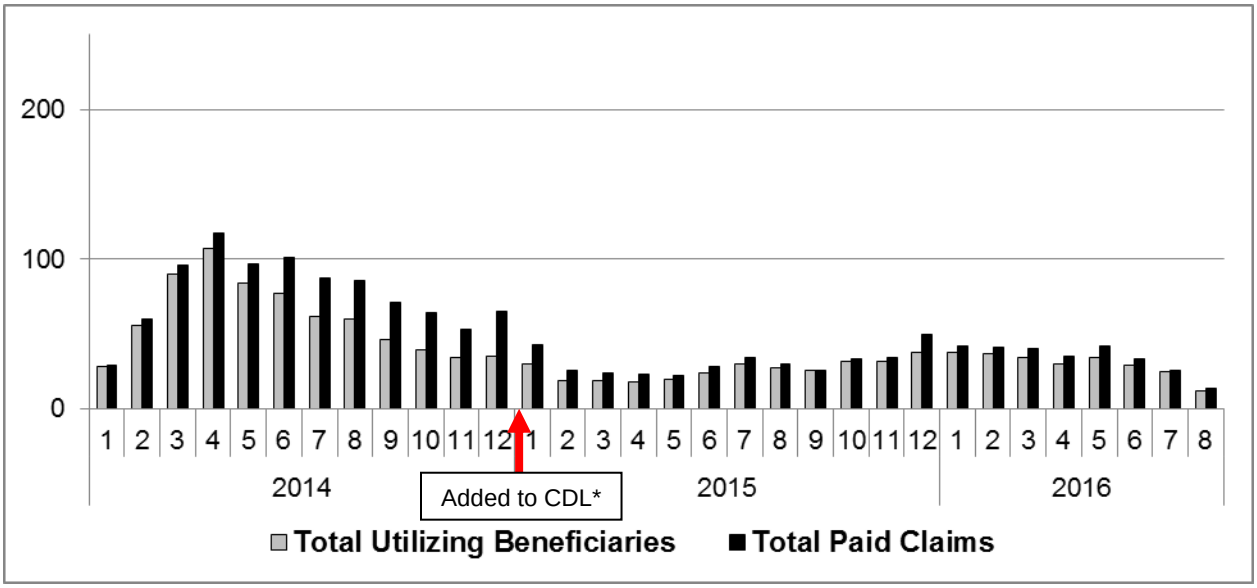
PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD: Review the utilization data (**Figures 1-10**) to determine if there is a need for further evaluation of any of the drugs added to the Medi-Cal List of Contract Drugs during the 2015 Federal Fiscal Year.

Figure 1. Ledipasvir/sofosbuvir (added January 1, 2015).



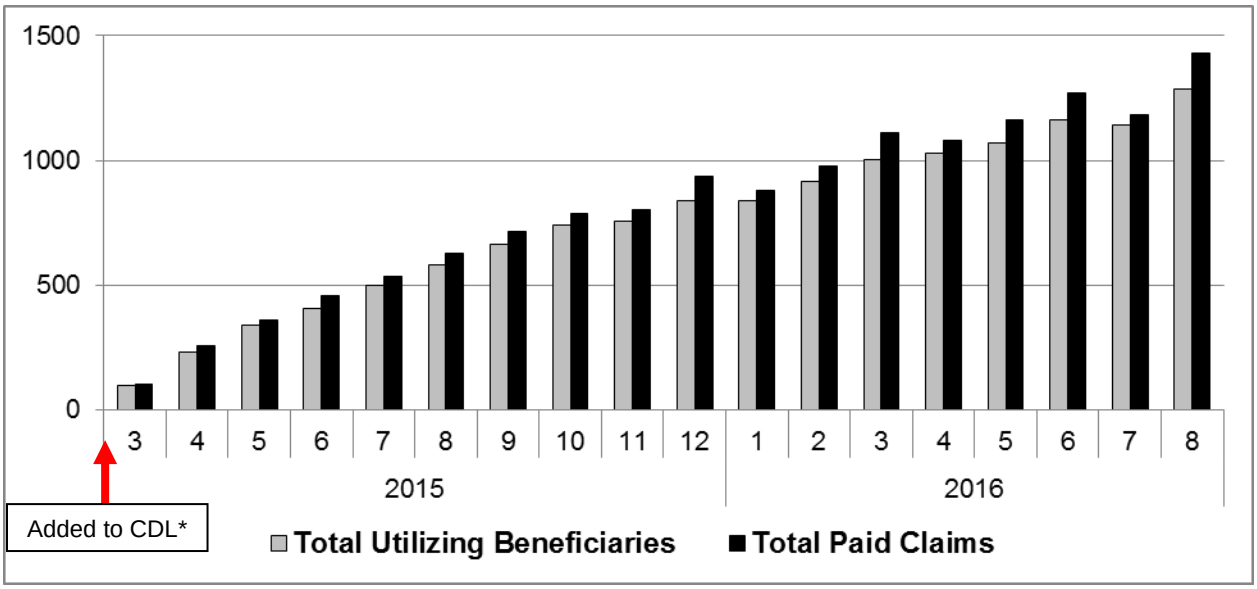
*During October 2014 there were < 10 utilizing beneficiaries.

Figure 2. Sofosbuvir (added January 1, 2015).



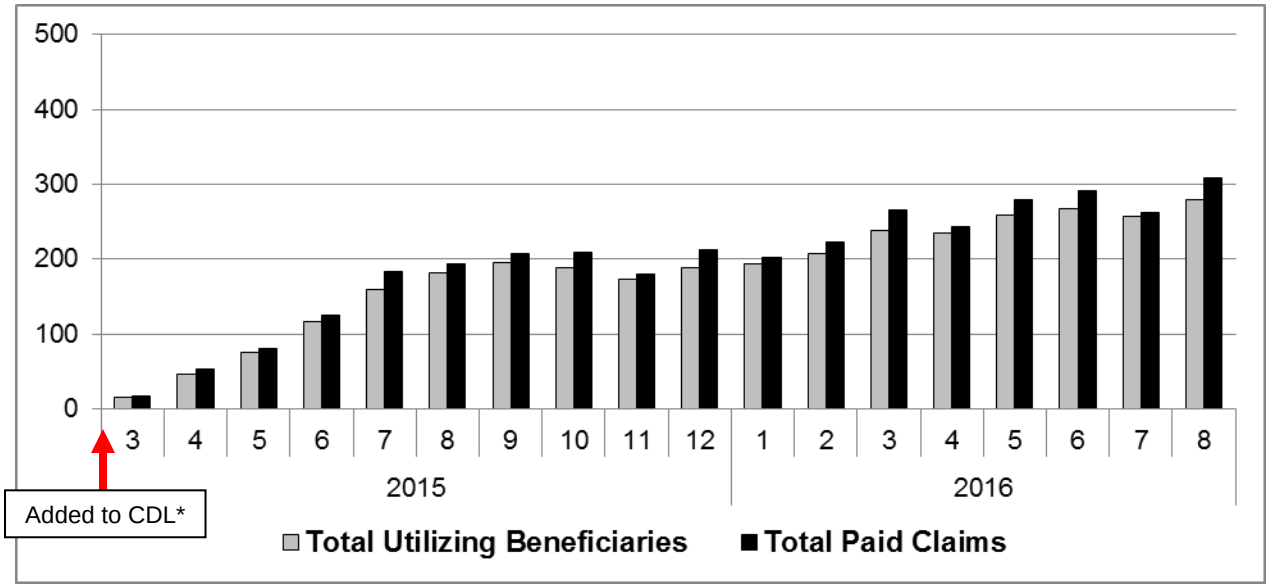
*During December 2013 there were < 10 utilizing beneficiaries.

Figure 3. Darunavir/cobicistat (added February 3, 2015).



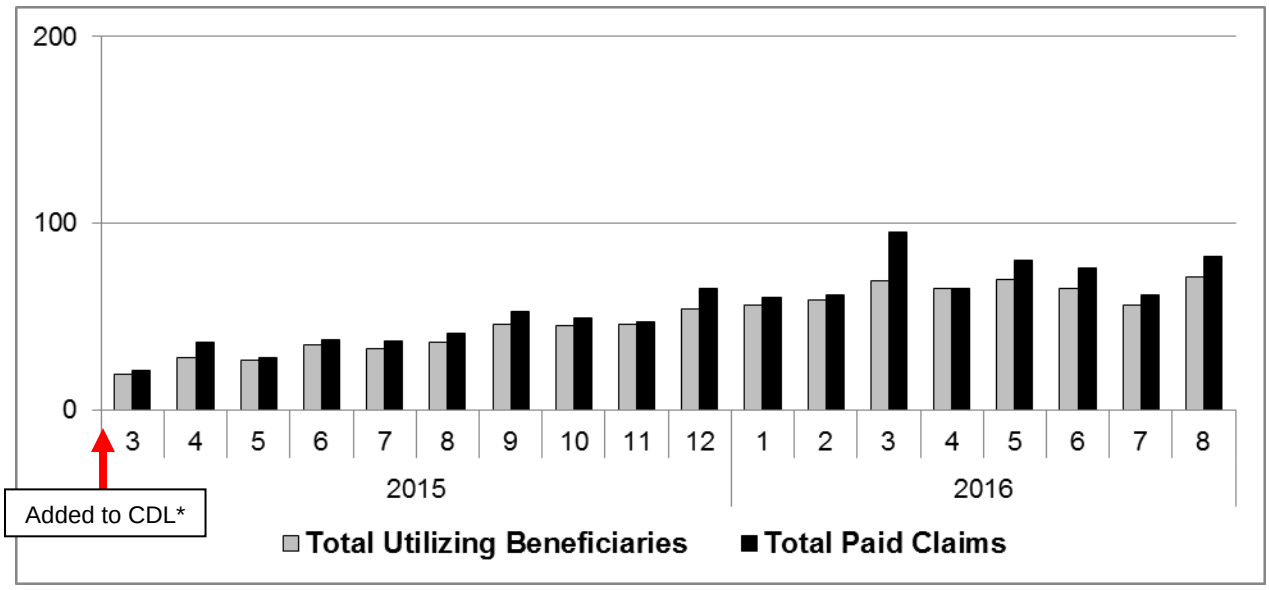
*During February 2015 there were < 10 utilizing beneficiaries.

Figure 4. Atazanavir/cobicistat (added February 6, 2015).



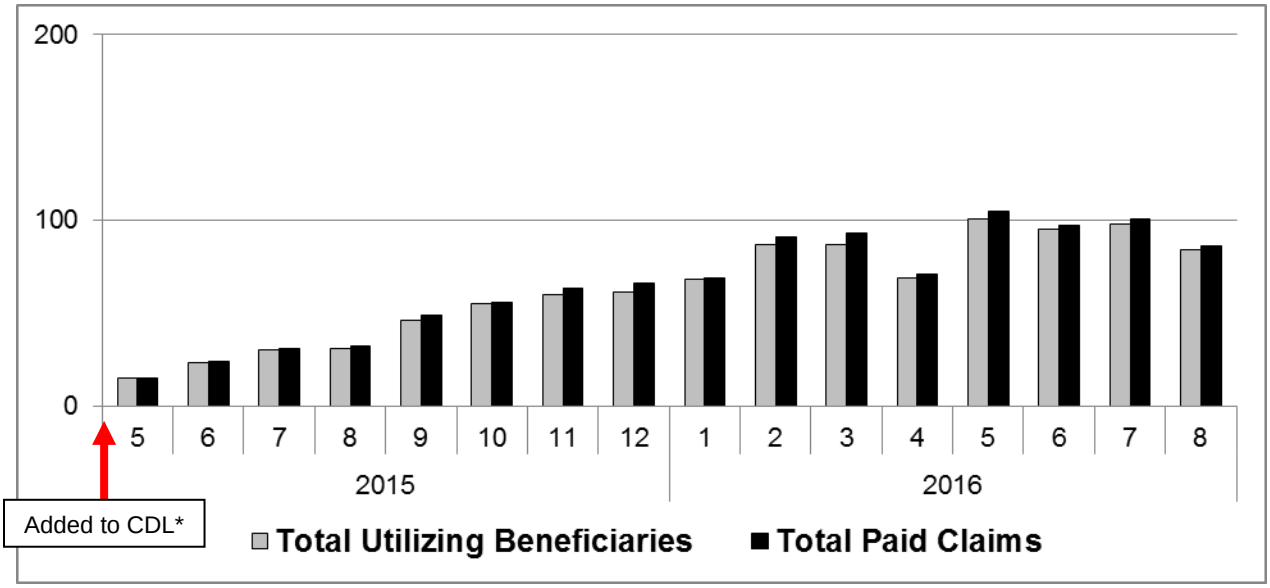
*During February 2015 there were < 10 utilizing beneficiaries.

Figure 5. Palbociclib (added February 9, 2015).



*During February 2015 there were < 10 utilizing beneficiaries.

Figure 6. Empagliflozin (added May 1, 2015).



*Between August 2014 and April 2015 there were < 10 utilizing beneficiaries.

Figure 7. Buprenorphine (added June 1, 2015).

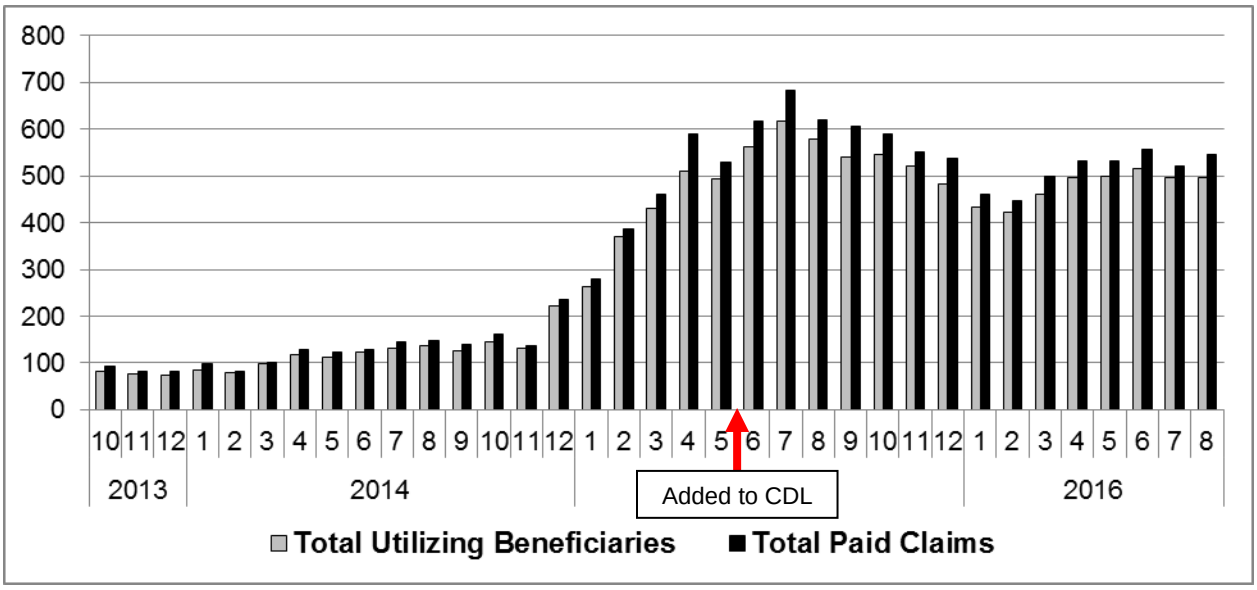
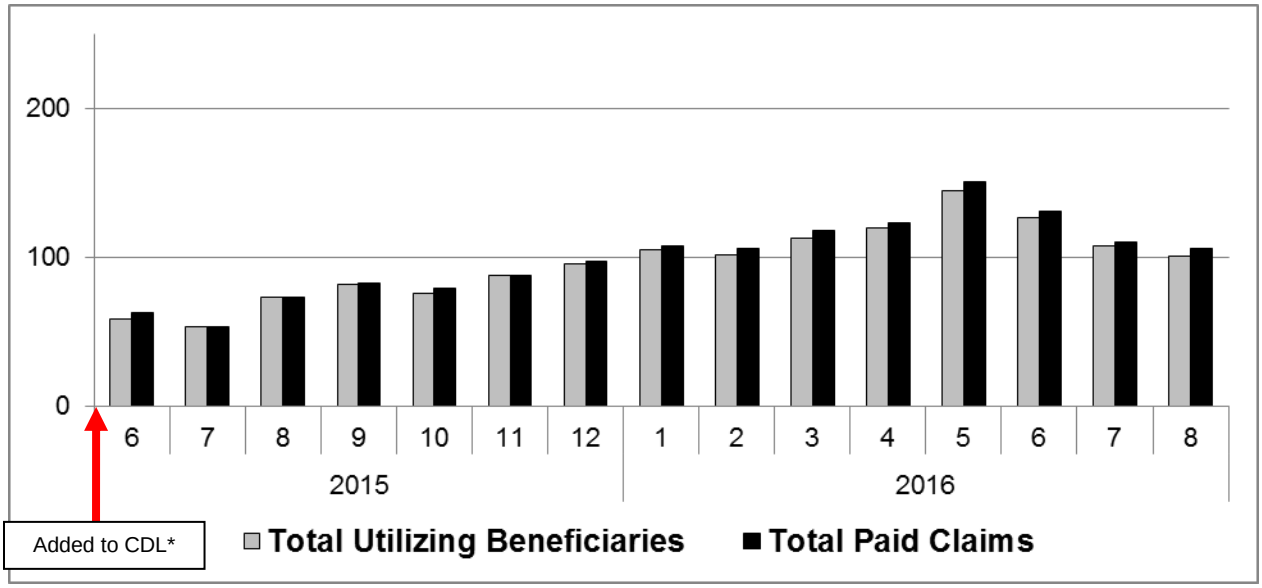
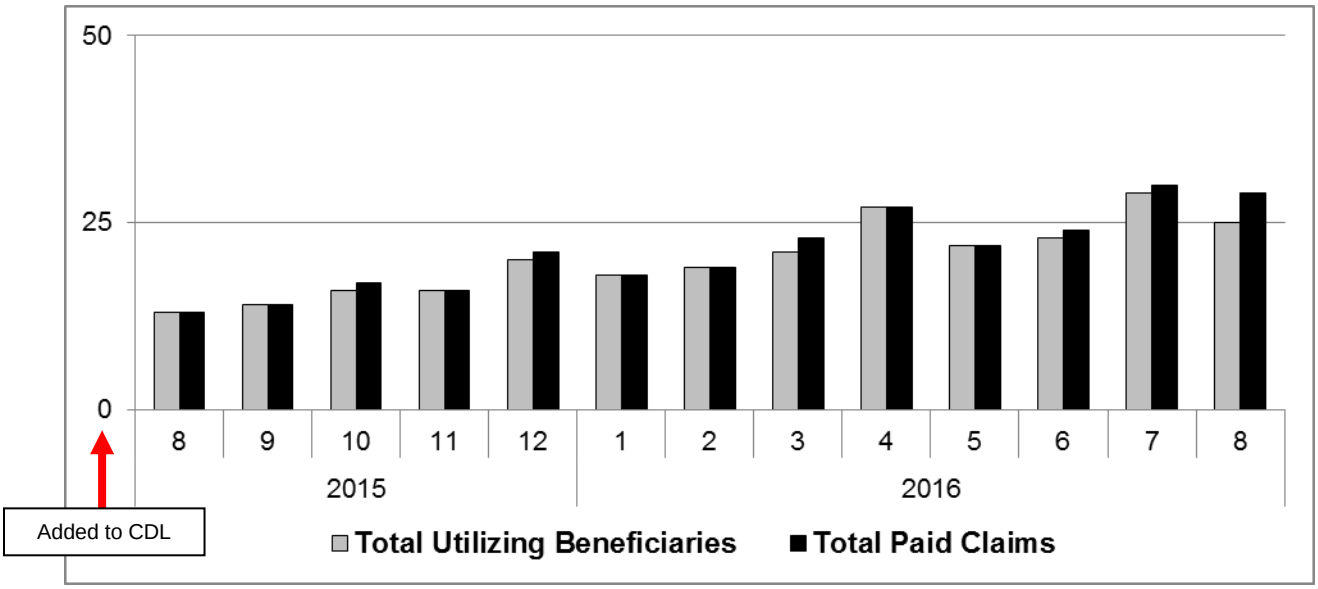


Figure 8. Dapagliflozin propanediol (added June 1, 2015).



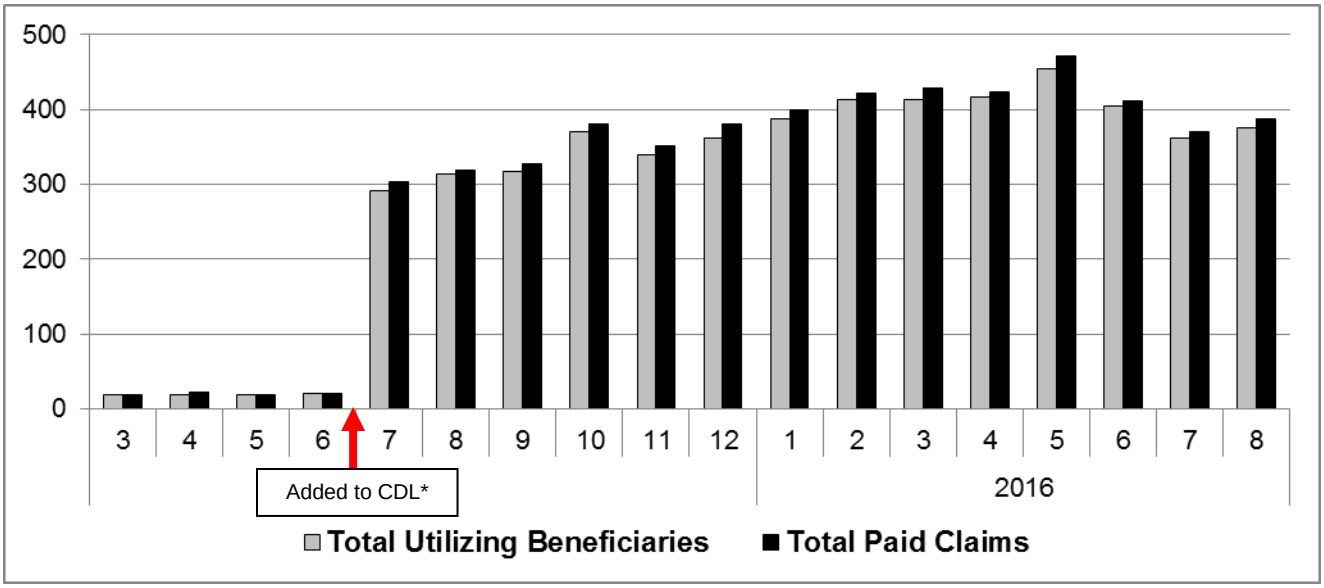
*Between May 2014 and May 2015 there were < 10 utilizing beneficiaries.

Figure 9. Dapagliflozin/metformin HCL (added June 1, 2015).



*Between June 2015 and July 2015 there were < 10 utilizing beneficiaries.

Figure 10. Etonogestrel/ethinyl estradiol (added July 1, 2015).



*Between October 2013 and February 2015 there were < 10 utilizing beneficiaries.

RETROSPECTIVE DUR REVIEW

DATE OF REVIEW: October 11, 2016

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- ANALGESICS, NARCOTICS
- ANTI-ANXIETY DRUGS
- SEDATIVE-HYPNOTICS, NON-BARBITURATE

DRUG PROBLEM TYPES: Drug-Drug Interaction (DD)

BACKGROUND: Each day in the United States, 46 people die from an overdose of prescription opioid pain relievers.[1] In recent years, there has also been an increase in concomitant dispensing of opioids and benzodiazepines, and a corresponding increase in combined benzodiazepine and prescription opioid misuse, abuse, and overdose, as measured by emergency department (ED) visit and overdose death rates.[2,3] Despite evidence that concomitant use of opioid analgesics and benzodiazepines are associated with serious adverse events including extreme sleepiness, respiratory depression, coma and death, one study found an increase of more than 2.5 million opioid users receiving concomitant benzodiazepines in 2014, compared with 2002.[2] Another study reported that opioids contributed to 77% of deaths where benzodiazepines were determined to be a cause of death, and, conversely, benzodiazepines contributed to 30% of deaths where opioids were determined to be a cause of death.[4]

ISSUE: On August 31, 2016, the U.S. Food and Drug Administration (FDA) announced that it will require class-wide changes to drug labeling, including patient information, to help inform health care providers and patients of the serious risks associated with the use of certain opioid medications in combination with benzodiazepines and other central nervous system (CNS) depressants.[5] The FDA will now requiring boxed warnings and patient-focused Medication Guides for prescription opioids, opioid-containing cough products, benzodiazepines, and other CNS depressants in order to help inform patients about the serious risks associated with concomitant use.[5]

Based upon customer feedback, as of October 26, 2016 First Databank (FDB) is proposing the addition of Severity Level 2 and Severity Level 3 drug-drug interactions for the following combinations:

- Severity Level 2
    - Opioids (Cough and Cold)/Benzodiazepines
    - Opioids (Cough and Cold)/ Sleep Drugs; Tranquilizers
    - Opioids (Cough and Cold)/Muscle Relaxants
    - Opioids (Cough and Cold)/Antipsychotics

- Severity Level 3
    - Opioids (Extended Release)/Benzodiazepines
    - Opioids (Immediate Release)/Benzodiazepines
    - Opioids (Extended Release)/Sleep Drugs; Tranquilizers
    - Opioids (Immediate Release)/ Sleep Drugs; Tranquilizers
    - Opioids (Extended Release)/Muscle Relaxants
    - Opioids (Immediate Release)/Muscle Relaxants

- Opioids (Extended Release)/Antipsychotics
- Opioids (Immediate Release)/Antipsychotics

Currently, in prospective DUR we only have Severity Level 1 drug-drug interactions turned on for the drug-drug interaction (DD) alert. The addition of these drug-drug interactions to Severity Levels 2 and 3 will mean that the proposed changes to the drug-drug interactions will not be captured in our current system.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: In order to evaluate the prevalence of concomitant use of opioids and benzodiazepines in the Medi-Cal fee-for-service program, all Medi-Cal fee-for-service beneficiaries with at least one paid claim for either an opioid or benzodiazepine between September 1, 2015 and August 31, 2016 (the measurement year) were reviewed.

During the measurement year, a total of 273,346 Medi-Cal fee-for-service beneficiaries (n = 492,649 total paid claims) had at least one paid claim for an opioid, including opioid-containing cough medication and a total of 47,774 beneficiaries had at least one paid claim for a benzodiazepine (n = 130,594 total paid claims). A total of 14,977 beneficiaries had at least one claim for both an opioid and a benzodiazepine during the year, representing 5.5% of beneficiaries with a paid claim for an opioid and 31.3% of beneficiaries with a paid claim for a benzodiazepine.

Among the 14,977 beneficiaries with a paid claim for both classes of drugs, a total of 6,355 (42%) had two or more paid claims for both an opioid and a benzodiazepine during the measurement year, and 479 (3%) beneficiaries had at least 12 paid claims for both an opioid and a benzodiazepine, suggesting continued use of both of these medications during the measurement year.

An additional review of pharmacy and medical claims for this group of 479 beneficiaries was conducted. As shown in **Table 1**, the majority of these beneficiaries have paid claims for at least one additional CNS depressant medication (n=380, 79%), most commonly a prescription sleep aid (44%) or a muscle relaxant (43%) during the measurement year.

Table 1. Review of pharmacy and medical claims for Medi-Cal fee-for-service beneficiaries with at least 12 paid claims for both opioid and benzodiazepine medications (between 9/1/15 and 8/31/16).

	n (%)
Any concomitant use of selected CNS depressant medications:	380 (79)
• Prescription sleep aids	209 (44)
• Muscle relaxants	208 (43)
• Antipsychotic medications	134 (28)
• Barbiturates	< 10 (2)
Medical claims with location codes for long-term care, skilled nursing facilities, or hospice:	210 (44)
Medical claims with diagnostic codes for cancer:	59 (12)

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Review the current policy proposed by First Databank for drug-drug interaction (DD) alerts. Discuss the risks and benefits of alternate mechanisms to capture high-risk prescribing, such as the additive toxicity (AT) alert, which triggers an alert after the fourth prescription of selected medications.

- Review and discuss the data presented regarding the concomitant use of opioids and benzodiazepines and determine if there is a need for further in-depth evaluation on this topic before moving forward with educational interventions.
- Discuss whether this topic merits either a DUR educational alert or bulletin. An alert would include only a brief summary of the FDA recommendations, while a bulletin would also incorporate Medi-Cal fee-for-service data and more extensive discussion regarding evidence-based clinical guidelines.
- Consider a DUR educational intervention targeting concomitant use of opioids and benzodiazepines, which may include patient profiles.
- Discuss the risks and benefits of including other CNS depressants (prescription sleep aids, barbiturates, muscle relaxants, and antipsychotics) in the patient profiles.

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Update: DUR Publications

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November 15, 2016

September 2016: DUR Educational Alert

2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus

- 2016 – 2017 Influenza Vaccine
  - Changes in both the influenza A (H3N2) virus component and the influenza B (Victoria lineage) virus in the trivalent vaccines
  - The federal Advisory Committee on Immunization Practices (ACIP) no longer recommends using live attenuated influenza vaccine (the “nasal spray” flu vaccine)
  - Recent study concluded that influenza immunization for pregnant women should be a public health priority due to risk reduction

September 2016: DUR Educational Alert - 1

2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus

- Meningococcal
  - Current serogroup C outbreak occurring in Southern California, primarily among adult men who have sex with men (MSM)
  - Since March 2016, at least 24 confirmed cases, including two fatal cases, have been reported among residents of Los Angeles and Orange counties
  - Quadrivalent meningococcal conjugate vaccines (MenACWY or MCV4) protect against serogroup C disease. CDPH recommends vaccination for all MSM residing in Los Angeles, Orange and San Diego counties, MSM who plan to travel to Los Angeles or Orange counties, and all HIV-infected persons in CA

September 2016: DUR Educational Alert - 2

2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus

- Tdap
  - Since January 2016 there have been 37 cases of pertussis in California among infants < 4 months
    - 12 mothers had not been vaccinated during pregnancy (6 did not remember a provider recommendation and 5 refused)
  - More focus should be put into provider and patient education about the significance of prenatal Tdap vaccination.
  - Women should get Tdap vaccination at the earliest opportunity between 27 and 36 weeks gestation of every pregnancy.

September 2016: DUR Educational Alert - 3

2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus

- Haemophilus b (Hib)
  - In January 2016, the United States Food and Drug Administration approved a new indication for Hib conjugate vaccine (tetanus toxoid conjugate) for a three-dose infant primary vaccination series at 2, 4, and 6 months of age
  - Expanding the age indication to include infants provides another vaccine option in addition to other currently licensed monovalent or combination Hib vaccines

September 2016: DUR Educational Alert - 4

2016 Immunization Updates: Influenza, Meningococcal, Tdap, Hib, Rotavirus

- Rotavirus
  - Currently, there are two rotavirus vaccines licensed for the US pediatric population (a 3-dose series and a 2-dose series)
  - ACIP guidelines recommend the same rotavirus vaccine series be completed with the same vaccine brand but allow for administering mixed vaccine types (using the 3-dose series)
  - A recent study of over 2,400 children found that mixing vaccine types to achieve a 3-dose series was just as effective as completing the series with only one rotavirus vaccine type.

Future Topics: Bulletins

DUR Educational Bulletins:

- Summarize use of antibiotics, with a special emphasis on new FDA safety warnings and the appropriate use of fluoroquinolone antibiotics
- Summarize relative risk of QT interval prolongation due to adverse drug reactions (in-progress)
- Promotion of appropriate prescribing of skeletal muscle relaxants, including an evaluation of concomitant use of opioids and benzodiazepines
- Provide treatment guidelines for managing pain in population with co-morbid mental health conditions, including those with a documented history of substance abuse
- Nicotine replacement therapy – to be timed with implementation of pharmacist furnishing of NRT
- Topics from today's meeting: HCV drugs, new additions

Future Topics: Alerts/Prospective Reviews

DUR Educational Alerts:

- Annual vaccine alert, including any updates on current guidelines (ongoing, published each September)
- FDA drug safety communications for drugs on the Medi-Cal List of Contract Drugs (ongoing)
- FDA black box warning for opioids and benzodiazepines/CNS depressants

Prospective DUR Reviews:

- Additive toxicity alert
- Therapeutic duplication alert
- Annual review of categories for duplicate therapy (Section 25, ongoing)
- Discrepancy clean-up (Section 20, ongoing)
- Quarterly review of new GCNs (ongoing)

Future Topics: Retrospective Reviews

Retrospective DUR Reviews:

- Proton-pump inhibitors (in-progress, on agenda for February 2017)
- Assessment of opioid use and mortality, linking death index information with medical/pharmacy claims data
  - Concomitant use of benzodiazepines
  - Gender disparities
- Annual review of drugs added to the Medi-Cal List of Contract Drugs (ongoing, presented each November)
- New 2016 Adult Core Set Measures:
  - Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD)
  - Use of Opioids at High Dosage (OHD)

UCSF

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Medi-Cal Drug Utilization Review Board Meeting Pharmacy Updates

Pauline Chan, R.Ph., MBA
Pharmacy Policy Branch
11-15-16

Topics

- CMS Updates:
  - Antipsychotic Drug Use in Children (ADC) Affinity Group Timeline
  - Combating Prescription Opioids Abuse: Actions from Four States
  - 2018 CMS DUR Annual Report Planning Committee
- Academic Detailing Conference & Follow Up Actions
- Medi-Cal Managed Care Pharmacy Directors' Meeting
- DHCS Quality Strategy Report to include DUR studies
- SB 238 Foster Care Psychotropic Medications
- Foster Care Psychotropic Medication Quality Improvement Project
- Improving access to prenatal vitamin use

Antipsychotic Drug Use in Children Affinity Group (ADC)

- Timeline/Commitment:
  - Monthly calls begins in March 2016 for 12 months
    - Quarterly all states call
    - Quarterly subgroup (Monitoring) call
    - Quarterly 1:1 call
- Learning Collaborative Topics:
  - Leverage the External Quality Review Organizations (EQRO) in monitoring antipsychotic medications
  - Individual state's specific strategies and challenges
- Project assignments submitted to date:
  - Driver diagram
  - Specific Aims
  - Baseline data (2014, 2015) HEDIS measures of APC and APM
  - Interventions to improve monitoring measure (APM)

Combating Prescription Opioid Abuse: Actions from Four Medicaid State Agencies

- Webinar on September 29, 2016
  - Georgia:
    - Task Force including physicians and pharmacists to provide expertise and to develop intervention strategies, data used includes PDMP
  - Maryland:
    - Corrective Managed Care (CMC) to identify over-users based on established criteria of number of Rx, the quantity dispensed, utilizing multiple prescribers and/or pharmacies

Combating Prescription Opioid Abuse: Actions from Four Medicaid State Agencies -2

- Michigan:
  - Neonatal Abstinence Syndrome Protocol
    - Preconception
    - Pregnancy
    - Post-natal (mothers)
    - Post-natal (infants)
  - Staff education at all levels, recognition, assessment, use of non-pharmacologic and pharmacologic treatments
  - Public Health campaign
  - Prescription surveillance

Combating Prescription Opioid Abuse: Actions from Four Medicaid State Agencies -3

– Wyoming

- Pregnancy and Narcotic Program (initiated in 2011)
  - Identified increasing number of pregnant patients who were reviewed for lock-in criteria
  - Process:
    - Drug Utilization Review Manager reviews list of patients and pharmacy claims, identifies over-users based on criteria (similar to Maryland's)
    - Write letters to obstetric provider if another provider prescribes
    - Reviews fetal opioids withdrawal cases

2018 CMS ADURS Annual Report Committee

- Jointly sponsored by CMS and the American Drug Utilization Review Society (ADURS)
  - First conference call on November 10, 2016
  - Feedback from Medi-Cal DUR board submitted
  - Next steps

Academic Detailing Conference

- Conference date: October 20, 2016
- Participating organizations: 14
- Supporting organizations: 6
- Conference evaluation
  - Speakers
  - Topics
  - Facility/organization
- Action Plan & Next Steps
- Academic Detailing Resources and Webpage
- Future collaboration with National Resource Center for Academic Detailing (NARCAD)

DHCS Quality Strategy Annual Report

- Opportunities to include DUR studies in DHCS Quality Strategy
  - Submission timeline: annually, next submission date summer of 2017

SB 238: Foster Care Psychotropic Medication

- Signed into law in October 2015 by Governor Brown
- Requires certification and training programs for care givers to include psychotropic medication, trauma and behavioral health, and addresses:
  - Authorization, uses, risks, benefits, assistance with self-administration, oversight, monitoring of psychotropic medication use, trauma, substance use and mental health services, including to access these treatments

- Requires Judicial Council to amend and adopt rules of court and develop appropriate forms (JV 220 process) for court authorization of psychotropic medication, by July 1, 2016

SB 238: Foster Care Psychotropic Medication -2

- Requires the California Department of Social Services (CDSS) in consultation with the Department of Health Care Services (DHCS), other agencies and stakeholders to implement provisions of SB 238
- CDSS and DHCS established SB 238 Psychotropic Medication Implementation (PMI) Workgroup
  - To develop county-specific monthly reports to include psychotropic medication data:
    - Up to date court authorizations
    - Pharmacy data (includes name of medication, dose, and quantity)
    - Use of Psychosocial interventions, concurrent or prior to psychotropic medications

SB 238: Foster Care Psychotropic Medication -3

(Continued)

- Monthly reports to include indicator that identifies each child under five years of age for whom one or more psychotropic medications is prescribed and each child of any age for whom three or more psychotropic medications are prescribed

– Monthly reports to be distributed to county placing agency, with data sharing agreement in place

– Develop a form to be used by county child welfare services agency to share with the juvenile court, the child's attorney, and the court-appointed special advocate, information pertaining to child served

Foster Care Psychotropic Medication QIP

- Initiated in July 2012 by DHCS and CDSS
- QIP's three workgroups completed deliverables
  - Clinical
  - Data & Technology
  - Youth and Family Education
- Merged all workgroups to the SB 238 Psychotropic Medication Implementation workgroup
- Continues tracking and trending of improvements and outcome

Improving Access to Prenatal Vitamin Use

- There are approximately 500,000 Medi-Cal births throughout the state each year
- Based on Medi-Cal pharmacy claims data, between July 1, 2015 to June 30, 2016, the number of unique Medi-Cal beneficiaries on pre-natal vitamins with folic acid:
  - Fee-For-Service 98,302 beneficiaries
  - Managed Care 122,779 beneficiaries
- Opportunities to improve access to pre-natal vitamin use
- Opportunities to collaborate with California Department of Public Health (CDPH) through outreach programs

Questions?

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